



IMPACT ASSESSMENT GUIDELINES

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INTRODUCTION

How to use these Guidelines?

These Guidelines are for Commission staff preparing impact assessments. They consist of a core text (this document) and annexes. The **core text** explains what IA is, presents the key actors, sets out the procedural rules for preparing, carrying out and presenting an IA, and gives guidance on the analytical steps to follow in the IA work. The presentation of the analytical steps distinguishes between the "what" to analyse, which is presented in boxes at the beginning of each chapter with the minimum requirements to be met, and guidance on "how" to carry out the analytical steps. The **annexes** contain more detailed guidance that may also be of help.

Additional guidance material, in particular on how to analyse specific impacts, is available on the Europa website, together with examples of good practice from past IAs. Links to these sites are available on the Secretariat General's IA IntraComm site¹.

Where to find more advice and support?

These Guidelines should provide answers to many of your questions. The IA support unit/function in your DG will also be a key source of help, and the desk officer who follows the work of your DG in the Secretariat General's Policy co-ordination units (SG directorate D) can also provide advice².

For questions related to stakeholder consultations, contact the "Transparency, Relations with Stakeholders and External Organisations" unit of the Secretariat General (SG.E.3).

The evaluation unit of DG Budget (BUDG.B5) will help if you have questions on the link between impact assessment and ex-ante evaluation required under the Financial Regulation (see section 1.4).

The Impact Assessment Board can also be consulted on methodological issues. For general questions, you should contact the Secretariat General's Better Regulation and Impact Assessment Unit (SG.C.2).

1. UNDERSTANDING IMPACT ASSESSMENT

1.1 What is impact assessment?

**Impact assessment is an *aid to political decision-making*,
not a substitute for it.**

Impact assessment is a set of logical steps to help you prepare policy proposals. It is a process that prepares evidence for political decision-makers on the advantages and disadvantages of possible policy options by assessing their potential impacts. The results of this process are summarized and presented in the IA report.

¹ See http://www.cc.cec/home/dgserv/sg/i/impact/index_en.htm

² See list of key IA contacts on http://www.cc.cec/home/dgserv/sg/i/impact/support_dg_en.htm.

In doing an IA, you will have to answer a number of questions:

- *What is the nature and magnitude of the problem, how is it evolving, and who is most affected by it?*
- *Should the Union be involved, and if so what objectives should it set to address the problem?*
- *What are the main policy options for reaching these objectives?*
- *What are the likely economic, social and environmental impacts of those options?*
- *How do the main options compare in terms of effectiveness, efficiency and coherence in solving the problems?*
- *How could future monitoring and evaluation be organised?*

The IA work is a key element in the development of Commission proposals, and the College of Commissioners will take account of the IA report when taking its decisions. The IA supports and does not replace decision-making - the adoption of a policy proposal is always a political decision that is made only by the College.

1.2 Why is it important?

**Impact assessment is a key tool
to ensure that Commission initiatives and EU legislation
are prepared on the basis of
transparent, comprehensive and balanced evidence.**

All policy-decisions should be based on sound analysis supported by the best data available. The Commission's impact assessment system helps the EU institutions to design better policies and laws. It facilitates better-informed decision making throughout the legislative process. It ensures early coordination within the Commission and it takes into account input from a wide range of external stakeholders, in line with the Commission's policy of transparency and openness. It helps to ensure coherence of Commission policies and consistency with Treaty objectives and high level objectives such as the Lisbon and Sustainable Development Strategies. It improves the quality of policy proposals by keeping EU intervention as simple as possible. Finally, it helps to ensure that the principles of subsidiarity and proportionality are respected, and to explain why the action which is being proposed is necessary and appropriate.

1.3 Who are the actors?

**While many actors may be involved in an impact
assessment,
the lead service
remains fully responsible for its quality.
The Impact Assessment Board provides support and advice,
and scrutinizes the quality of all impact assessments.**

The lead service which is developing the proposal is responsible for developing the impact assessment. It will of course seek the input of stakeholders and in many cases involve internal and external expertise. It is supported by other Commission services,

including the Secretariat-General, through the impact assessment steering groups and the inter-service consultation. The Impact Assessment Board, which will control the quality of your IA, can also provide support and advice on your report before it is finalized.

1.4 When is an impact assessment necessary?

These guidelines do not define which Commission initiatives need to be accompanied by an IA. This is decided each year by the Secretariat General/Impact Assessment Board and the departments concerned. In general, impact assessments are necessary for the most important Commission initiatives and those which will have the most far-reaching impacts. This will usually be the case for any item which is part of the Commission's Legislative and Work Programme (except for initiatives of a consultative or purely reporting nature), but it will also be the case for certain catalogue items and comitology items. You should establish at an early stage of the planning process, in consultation with the Secretariat General and the Impact Assessment Board, whether your initiative is likely to need an impact assessment. You should also establish at an early stage what scope and level of analysis would be proportionate to the significance of the corresponding initiative (see chapter 3 below).

Link between IA and ex-ante evaluation

Some initiatives will be financed from the Community budget, and will need an ex ante evaluation in line with Article 21(1) of the implementing rules of the Financial Regulation³. If an impact assessment is also considered to be necessary for such an initiative, it is important to avoid duplication of efforts. As long as the impact assessment addresses the points listed in Article 21(1), a separate ex ante evaluation is not required⁴. You will need to pay particular attention in the IA, however, to the cost-effectiveness of the various options reviewed (see section 5.5.3). If your proposal does not need an impact assessment, but does have budgetary implications, then you will of course need to do an ex ante evaluation. If you are not sure whether an IA or an ex-ante evaluation is more appropriate, you should contact DG Budget's evaluation unit or unit C2 in the Secretariat General.

³ COUNCIL REGULATION N° 1995/2006 of 13.12.06 amending Regulation N° 1605/2002 on the Financial regulation applicable to the general budget of the European Communities (OJ L 390/2006 of 30.12.06, and COMMISSION REGULATION No 478/2007 of 23.04.07 (OJ L 111 of 28.04.2007)

⁴ The latest revision of the Implementing Rules has brought the requirements for ex ante evaluations closer to those for impact assessment presented in these guidelines. cf. SEC(2007)213, 21.02.07 "Responding to Strategic Needs: Reinforcing the Use of Evaluation."

2. WHAT ARE THE PROCEDURES?

Summary of key procedural steps

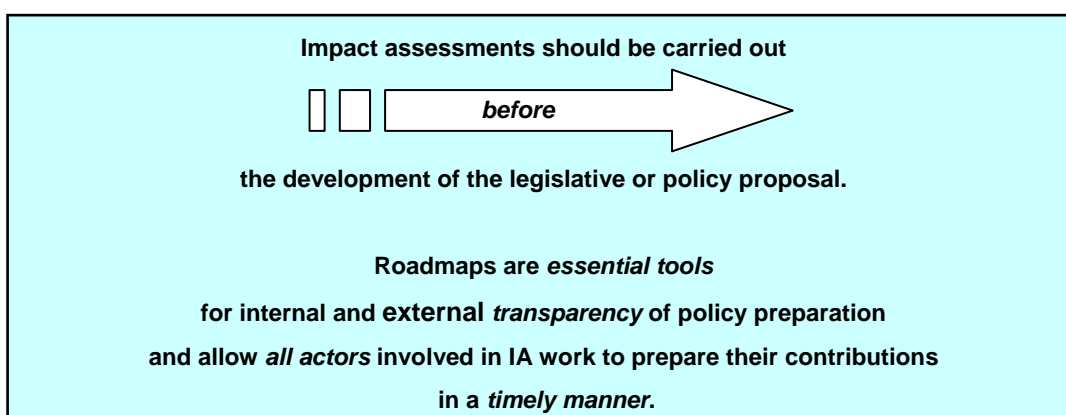
- **Planning of the impact assessment/integration in the SPP cycle:**
 - Establish the Roadmap for the initiative for inclusion in the CLWP.
 - Where relevant, discuss the initiative 'upstream' with the SG/IAB.
- **Set up an Impact Assessment Steering Group (IASG):**
 - Compulsory for all items, exceptions to be clearly justified
 - Include the relevant SG.D unit
- **Consult interested parties and collect expertise.**
- **Carry out the IA analysis.**
- **Present the findings in the IA report even if the initiative is withdrawn.**
- **Present the draft IA report to the Impact Assessment Board (IAB).**
- **Finalise the IA report in the light of the IAB's recommendations.**
- **IA and IAB opinion go into Inter-Service Consultation alongside proposal.**
- **Submission to the College of Commissioners.**
- **Transmission of the IA report alongside the proposal to the other Institutions.**

Press release should mention the IA.

- **Final report and IAB opinion published on Europa website by SG.**

In the light of new information or on request from the Council or the EP, the Commission may decide to update the IA report → contact SG.C.2.

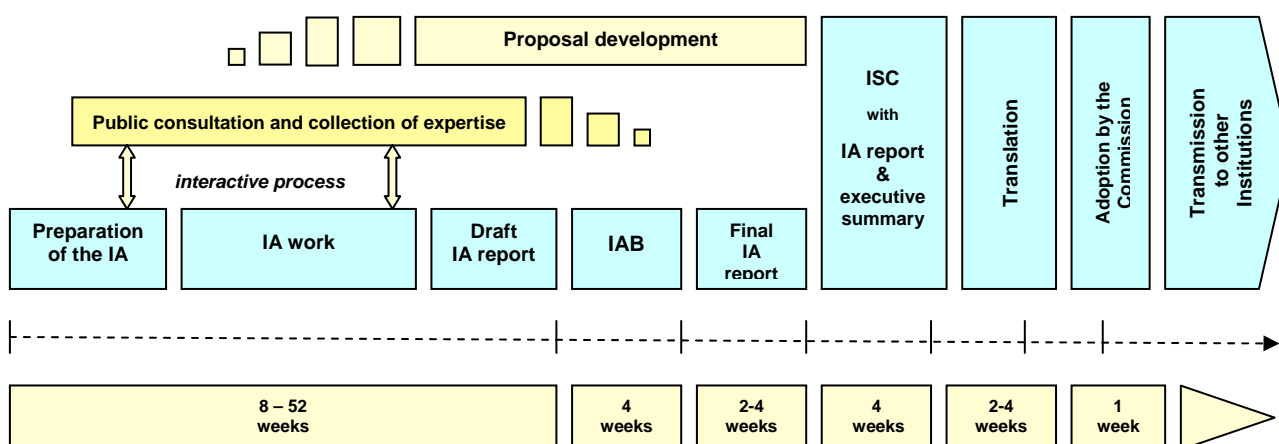
2.1 Planning the IA: The Roadmap and the SPP cycle



As impact assessments require time and resources, planning for them is integrated into the Commission's annual Strategic Planning and Programming cycle.⁵ All initiatives which are included in the Commission Legislative and Work Programme (CLWP) must be accompanied by a Roadmap⁶ which should include brief information on each of the analytical steps and the timing of the IA. It should indicate which DGs will be invited to the impact assessment steering group. It should also outline a consultation plan (see also chapter 4.3). You should circulate your Roadmaps, even in an early form, to other DGs well before the adoption of the WP. This will allow them to plan how to contribute to the impact assessment and to ensure coherence with their own policy objectives. As the Roadmaps are published in parallel with the CLWP, they allow external stakeholders to prepare their input to the process. The Secretariat-General and the IAB also screen the Roadmaps to identify those initiatives that would benefit from up-stream quality support.

Given that it can take several months to carry out the various steps of an impact assessment, including the minimum periods needed for public consultation, planning will in most cases have to start well before the CLWP/ Roadmap exercise. The following chart gives you an overview and indicative timing of the steps between planning an IA and adoption of the related proposal. Annex 2 provides further guidance on this.

Typical countdown for preparing an impact assessment



⁵ Cf. http://ec.europa.eu/atwork/index_en.htm

⁶ The current Roadmap template is presented in annex 1.

2.2 Impact Assessment steering groups (IASG)

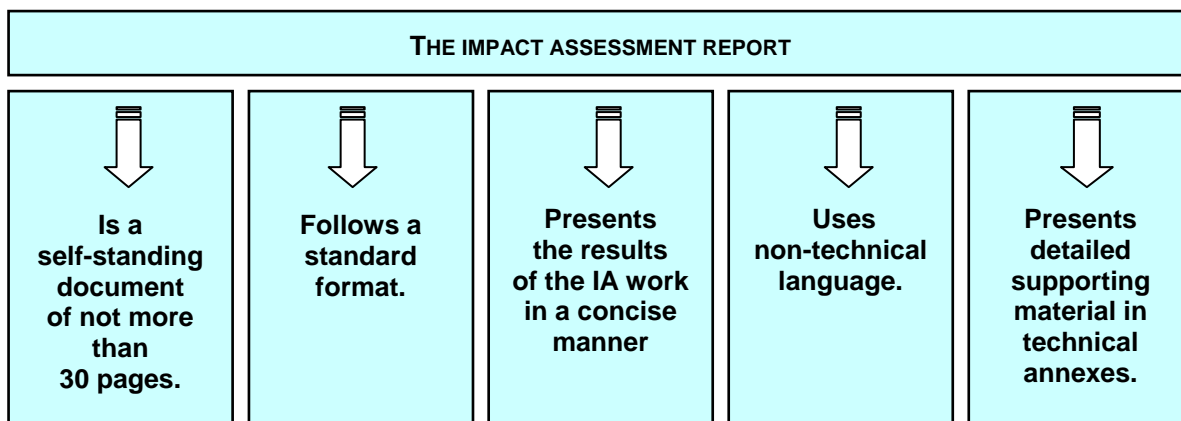
AN IMPACT ASSESSMENT STEERING GROUP should be set up for each impact assessment and should be fully involved in all phases of the impact assessment work.

You must set up an impact assessment steering group for each impact assessment you have to do. Exceptions are only possible if the proposal is of very narrow scope and has no impacts on other policy fields. Existing inter-service groups – for example to accompany a study that feeds into the IA work or for the development of the proposal - can be used to steer the IA work.

Composition: You should include in the IASG the DGs whose policies are likely to be affected by your initiative, and you should always invite the relevant policy coordination unit of the SG (Directorate D). You should use fully the expertise available in other DGs to ensure that all relevant impacts of your policy options are assessed. The IASG is also the best way for other services to ensure that their views are taken into account. It is therefore important that services participate actively in the steering groups and plan participation well in advance. This process should also make it easier to reach agreement during the Inter-Service Consultation.

Timing: You should set up the IASG at the beginning of the work, and involve it in all phases, including preparatory studies, consultation, and drafting of the report.

2.3 Presenting the findings: The IA report



The report should present the results of the IA process in the following **format** (more guidance is available in Annex 2):

- Executive summary
- Section 1: Procedural issues and consultation of interested parties
- Section 2: Policy context, problem definition and right to act
- Section 3: Objectives

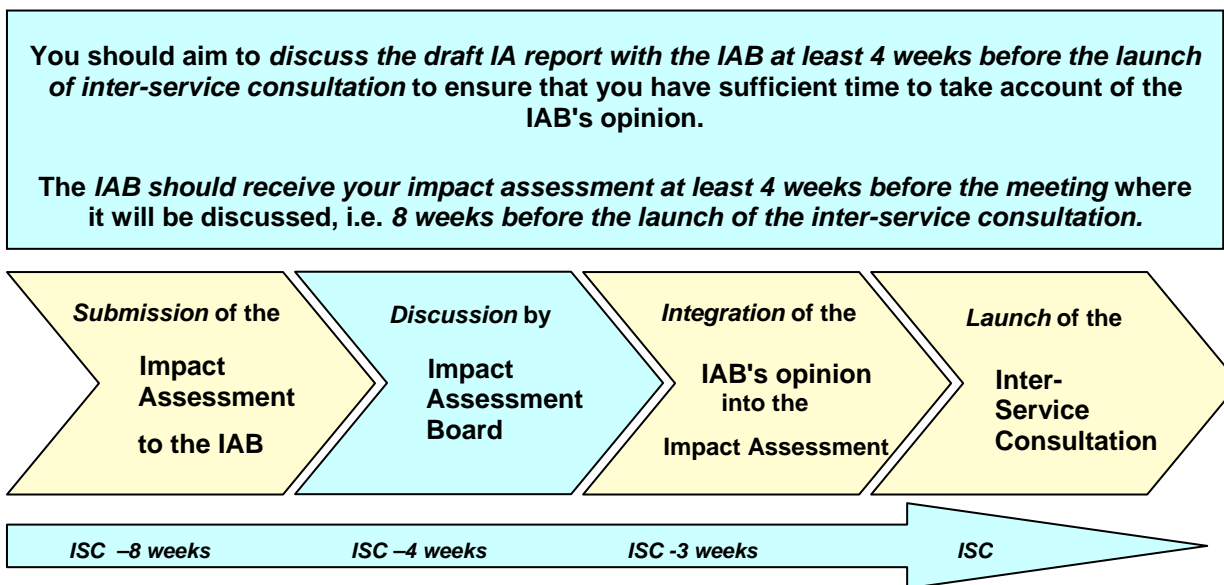
- Section 4: Policy options and analysis of their impacts
- Section 5: Comparing the options
- Section 6: Monitoring and evaluation

The report should be no more than 30 pages of text (excluding the executive summary, tables, diagrams and annexes). If the IA report covers several initiatives, you may need to go beyond 30 pages. You should discuss this at an early stage with the IAB secretariat (SG.C.2). Supporting documents, such as results of studies, expert reports or summaries of stakeholder views, should be presented in annexes.

- The report must nevertheless be a **self-standing document** which presents the analysis and all relevant results of the IA work, including summaries of information that are presented in annexes.
- You should provide an **executive summary** of no more than 10 pages. It should a) present a summary of the problem description and the objectives; b) list the range of options identified and the options assessed in detail; c) present the main economic, social and environmental impacts of each option and, where relevant, d) the result of the comparison of the options, indicating the criteria for comparison. For points c) and d) the executive summary should contain, where available, a clear presentation of any quantified benefits and costs of the various options, including compliance costs, costs for administrations and administrative burden.
- You should submit the executive summary and the main report together to the IAB. The final versions of these texts should be presented to the College as two separate Staff Working Documents.
- The report should be **written in clear and simple language**. Any non-specialist reader should be able to follow the reasoning and understand the impacts of each of the options. To enhance the clarity and readability of the report, tables and diagrams should be used to summarize key points.
- The report can be drafted in English, French or German, and is generally not translated. The executive summary must, however, be **translated** into all official languages.
- The IA report should have a **disclaimer** on the cover page, and should also indicate in the introduction, that the report commits only the Commission services involved in preparing it, and that the text is a basis for discussion and does not prejudge the final decision to be taken by the Commission.

NB: You should produce an IA report even when the conclusion of your analysis is that you should not proceed with a proposal. These IA reports should explain why it was decided not to take action. The IAB will examine them, and they will be published on the Europa website.

2.4 The Impact Assessment Board ⁷

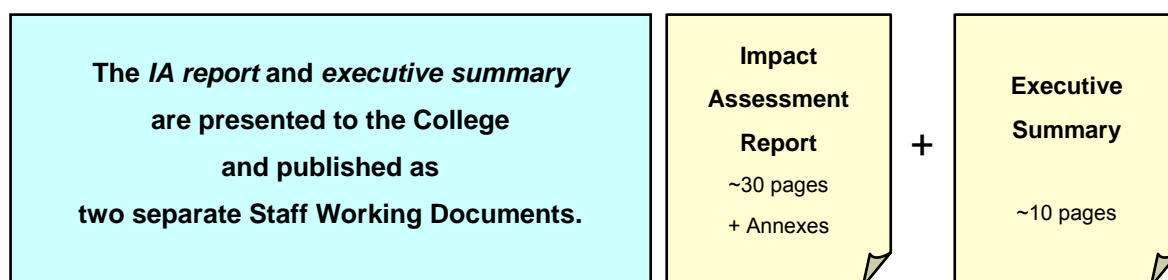


Upstream advice: You can already seek advice from the IAB on your IA at an early stage of preparations, for example on methodology or on the depth of analysis that is likely to be proportionate for your initiative.

Quality control: The IAB must give an opinion on your IA report before you put it into inter-service consultation (ISC). Given that the IAB may ask to see a revised version of your initial report, you should plan the timing carefully. You should aim to discuss the IA report with the IAB at least 4 weeks before the start of the ISC to leave you time to take fully into account the IAB's opinion. You should also submit the IA report to the IAB 4 weeks before the meeting in which you plan to discuss it.

The issues which the IAB will analyse when carrying out its quality assessment are published on the IAB IntraComm site⁸.

2.5 Inter-service consultation, presentation to the College and publication of the IA report



If the IA confirms that action is necessary, a proposal will be drafted and put into ISC, together with the IA report (including annexes) and the IAB opinion. You may need to make final adjustments to the IA report to take on board comments made during the ISC.

⁷ For more information on the IAB see http://www.cc.cec/iab/i/index_en.cfm

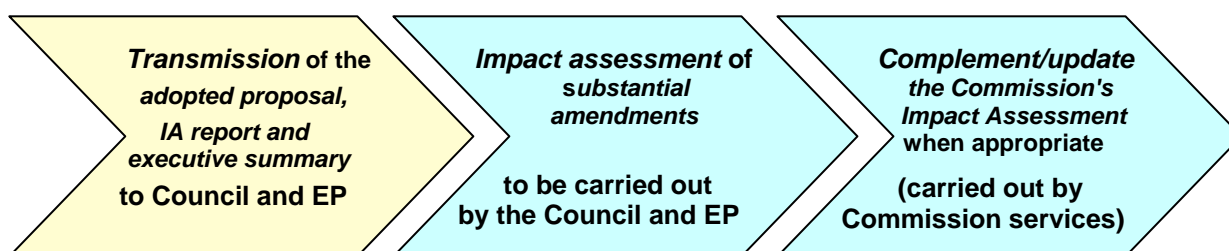
⁸ Cf. http://www.cc.cec/iab/i/index_en.cfm#key_docs No. 5.

In addition, the Explanatory Memorandum accompanying the draft proposal should set out briefly the options that have been considered, their potential economic, social and environmental impacts, and the website address where the final IA report can be found⁹.

After ISC, the IA report and the executive summary are submitted to the College of Commissioners with the draft proposal.

The SG will publish the final IA report on the Europa IA website along with the proposal and the IAB opinion. In certain cases, such as when information is confidential and sensitive, a decision to restrict or delay the publication may be considered. You should consult the Secretariat General (SG.C.2) for further guidance on this.

2.6 Use of the IA report by the Council and Parliament



The proposal and the final IA report are transmitted to the other Institutions, and you should use it actively when presenting the merits of the proposal during the legislative process.

Both Council and the European Parliament have made a commitment to assess the impact of substantial amendments they make to Commission proposals.¹⁰ Your impact assessment should try to anticipate as best as possible issues that are likely to be raised

in Council and Parliament, for example the choice of instrument for EU action. In the light of new information, the Commission may decide on a case by case basis to update the original impact assessment. In all such cases, it is important to consult the Secretariat General as early as possible (SG.C.2)

⁹ See explanatory memorandum http://www.cc.cec/home/dgserv/sg/em/index_en.htm.

¹⁰ See the Inter-Institutional Common Approach for Impact Assessment, Council Doc. 14901/05 of 14.11.05 . http://ec.europa.eu/governance/better_regulation/ii_coord_en.htm#_iia .

3. HOW TO DEFINE THE SCOPE OF THE IA AND THE LEVEL OF ANALYSIS WHICH IS PROPORTIONATE

Challenges

- Legal constraints or previous political choices relevant to the scope of the IA (in terms of objectives and options analysed) must be explained in the section on policy context.
- The level of analysis which is proportionate relates to the entire IA process, including for example data collection, provisions for stakeholder consultation and quantification of impacts.
- Defining the level of analysis for your initiative needs to be carried out for each IA individually and may be an iterative process. Guidance for typical cases is available (see 3.3).

Criteria for defining the level of analysis which is proportionate:

- **Significance of likely impacts:** The more significant the impacts are likely to be, the deeper the analysis should be.
- **Political importance:** The IA should provide sufficient evidence to respond to concerns that are likely to arise in the decision-making process, or the public reaction after the initiative is adopted by the Commission.
- **Situation in the context of policy development:** requirements for the IA will change depending on whether or not the initiative is in a policy field where EU-action already exists and whether (parts of) the initiative have been analysed in an earlier IA or will be analysed at a later stage in a follow-up IA.

NB: Regardless of the level of analysis the impact assessment contains, the report should follow the standard format outlined in section 2.3.

3.1 Legal constraints or political choices influencing the scope of the analysis

The scope of an IA can be influenced by legal constraints or previous political choices. Where such limitations result from the legal context, i.e. limitations/obligation for EU action fixed in primary or secondary EU legislation or international law, the IA should explain why certain policy options are necessary or not feasible. In such cases, the IA will need to place a strong emphasis on the subsidiarity/proportionality issues in the description of options.

Council or Parliament may also have expressed a preference for a certain form of action. The Commission should nevertheless analyse all relevant options for action. On the basis of this analysis, the Commission may conclude that the action preferred by the other Institutions has drawbacks that can be avoided by choosing an alternative option (including 'no new action'). In such cases you will have to provide strong evidence and analysis in the IA to explain the choice of the proposed option.

In general, political mandates, previous political choices or political expectations by EU-Institutions, Member States or stakeholders should not *per se* be presented in an IA report as reasons to dismiss a relevant and feasible option without further analysis. The origin and rationale of earlier political choices for the scope of the IA should be explained in all cases.

3.2 Criteria for defining the proportionate level of analysis for an impact assessment

NB: The "**proportionate level of analysis**" for an IA relates to the degree of effort which is necessary for the different steps of impact assessment. It should not be confused with the "**principle of proportionality**" which is examined in relation to options for EU action to show that the action does not go beyond what is needed to achieve the objectives (cf. section 5.3.2).

An IA should provide decision-makers in the EU-institutions with solid evidence on the impacts and advantages and disadvantages of a range of policy options, but it should also avoid unnecessary effort. It should not go into a level of detail or areas of analysis that would not lead to further relevant insights or alter the conclusions or their certainty.

The "proportionate level of analysis" is not only about the depth and scope of the analysis or the drafting of the IA report. It refers to the whole IA process - data collection efforts and stakeholder consultation, the level of ambition of the objectives, options and delivery mechanisms, the type of impacts to be examined, and the arrangements for monitoring and evaluation. You should note that even if you decide to carry out an IA which is relatively limited in terms of depth and scope, you should nevertheless produce a report which follows the standard structure presented in section 2.3.

It is the responsibility of the author service to determine the level of analysis. You should do this as early in the planning process as possible, taking into account that your assessment of what is proportionate may change as your analysis evolves.

The following paragraphs provide some guidance for this task, and advice is also available from the IA steering group, the Secretariat-General and from the IAB.

In defining the right level of analysis for your IA, you should think about the following questions:

- How significant are the likely impacts?
- How politically important is the initiative?
- Where is the initiative situated in the context of policy development?

3.2.1 Significance of impacts

An initiative may have a particularly significant impact in one or more of the fields analysed in the impact assessment (economic, social or environmental). It may also have impacts on certain economic sectors, on economic actors, groups of citizens, on businesses, SMEs, or citizens, fundamental rights, or on regions, species or habitats. Other issues may also be relevant – the impact on a third country or the contribution to Commission programmes such as the programmes for simplification of legislation or for the reduction of administrative burdens.

The first step in deciding whether these impacts merit special attention in the IA will be in the IASG on the basis of past experience, observation of markets and political developments etc.¹¹

¹¹ This preliminary test of impacts will feed into step 1 of the impact analysis described in chapter 5.4.2.

3.2.2 Political importance

You can assess the political importance of a Commission initiative by answering the following questions:

- Does the initiative relate to Commission strategic or annual priorities (such as promoting growth and jobs, promoting energy efficiency) and/or does it cut across several policy fields?
- Could the initiative raise subsidiarity/proportionality concerns?
- Is it particularly controversial? Who might contest the initiative?
- Has the initiative a particular importance in the inter-institutional context or for certain Member States?

In such cases, you should present particularly solid evidence in the IA to underpin the Commission's action, and anticipate amendments or alternative solutions that may be raised in the decision-making process.

3.2.3 IA and the stages of policy development

The level of analysis which is proportionate for an IA is also linked to the stage in the process of preparing an initiative. This process can stretch from a Green Paper, via a White Paper, possible presentation of an Action Plan, and finally the presentation of a legislative proposal. If decisions on EU-action are carried out in steps, the IA should only assess those elements of the initiative which are new compared to the previous step. An IA for a specific legislative proposal, for example, should be able to draw on previous analytical work, data collection, and preliminary estimates from the IA of the strategy or action plan that it implements. If the problem description and objectives are already available, you should not repeat them but only update them if necessary. Likewise, in an IA for a comitology decision you should not repeat the analysis of the IA for the basic legislation (if it exists) but rather focus on the actual decision at stake. In all these cases, you need to set out clearly the link with other assessment work.

However, if an initiative breaks new ground, you will have to explain its rationale and analyse its impacts more thoroughly than would be the case for established policies or for legislation which is a follow-up to existing legislation. In such cases, the IA report should provide a thorough description of the policy context and problems, and demonstrate clearly the necessity and added value of EU action.

Initiatives in "new" areas of existing policy fields need to analyse a credible range of options for action (including a "scale back" option, "no new action" option, non-legislative action and, where applicable, different options for legislative action).

3.3 Guidance for defining the proportionate level of analysis for different types of initiative

3.3.1 Types of initiatives

For each impact assessment, it will of course be the content rather than any formal classification that determines the degree of analysis needed. For guidance purposes, however, you might consider six categories of initiative.

- ♦ **Communications which give broad policy orientations**, or general directions for action but which do not propose concrete actions. (e.g. Communication on Quality of Teacher Education in the EU)

- ♦ **Non-legislative initiatives/ White papers which set out commitments for future action**, such as the Thematic Strategy on Air Pollution; Action Plan for biomass;
- ♦ **"Cross-cutting" legislative action**, such as regulations and directives that address broad issues and are likely to have significant impacts in at least two of the three pillars (economic, environmental and social) and on a wide range of stakeholders across different sectors (e.g. Regulation on motor vehicles emissions; Directive on the legal framework for payments)
- ♦ **"Narrow" legislative action** in a particular field or sector, and unlikely to have significant impacts beyond the immediate policy area (e.g. Framework Decision on procedural rights in criminal proceedings; Directive on common rules and standards for ship inspection and survey organisations)
- ♦ **Expenditure programmes**: Decisions to establish or renew spending programmes (e.g. Decision to establish the programme "Citizens for Europe" to promote active European citizenship; General Programme Solidarity and Management of Migration Flows)
- ♦ **Comitology decisions**: different executive initiatives defined by the procedure of adoption, of a "quasi-legislative" nature.

3.3.2 Guidance for different types of initiatives

The following table identifies illustrates how impact assessments may differ for the types of initiatives presented in section 3.3.1. It will often be the case that the exact form of your initiative will only become clear in the course of the assessment of the different options. Once the preferred option(s) emerge from the analysis, the guidance below, together with the three criteria in chapter 3.2, will help you to establish the right level of analysis for your IA.

IA SHOULD FOCUS ON:	IA SHOULD AVOID EXCESSIVE EFFORT ON
Communications giving broad policy orientations (without envisaged action or with only general outline for action)	
<ul style="list-style-type: none"> • Concise problem definition and clearly linked, detailed identification of objectives of initiative. • Subsidiarity and proportionality analysis (clearly explain necessity and added value of EU action). • Exploration of different approaches and possible instruments for achieving the objectives. • Identification and (usually) qualitative description of the most significant potential impacts of different approaches or instruments, clearly linked to the objectives; thereby focus on trends, causalities and mechanisms. • Identification of need for follow-up IAs if more concrete action is recommended. 	<ul style="list-style-type: none"> • Objective setting: set general and specific objectives; operational objectives only where possible and pertinent. • Description of policy context and objectives should avoid duplication of Communication. • Analysis of "no EU policy" and "no change" options should be short and avoid merely repeating the problem description. • Only brief overview of possible monitoring and evaluation approaches, if pertinent including indicators reflecting general objectives. • Don't write more than 10 pages IA.

Non-legislative initiatives / Strategy papers, which set out commitments for future action (such as White Papers and action plans)	
<ul style="list-style-type: none"> • Identification of general and specific objectives and, as far as possible, operational objectives. • Subsidiarity and proportionality analysis (clearly explain necessity and added value of EU action) • Identification of different options for action, including clarification of instruments to implement broad options, level of ambition, etc. • Identify alternatives for the individual actions which are planned. • Assessment of potential impacts in the 3 pillars • Identification of need for follow-up IAs for future actions if impacts cannot be fully assessed at this stage. • Identification of broad monitoring and evaluation arrangements. 	<ul style="list-style-type: none"> • Description of policy context and objectives should avoid duplication of Communication. • Analysis of "no EU policy" and "no change" options should be short and avoid merely repeating the problem description.
Cross-cutting legislative action	
<ul style="list-style-type: none"> • Detailed description of problems/ challenges that necessitate EU legislation, and how they are likely to evolve. • Identification of options in line with minimum standards, including self- and co-regulation. • If the range of feasible options is limited by political constraints or previous policy, analyse different implementation options, levels of ambition, and/or choices of instruments. • Thorough assessment for all options of impacts in relevant pillars; justify non-consideration of a pillar. • In case of a simplification initiative: clearly spell out the simplification benefits. • Always consider the impact on administrative burden (positive or negative). • Monitoring and evaluation arrangements to include indicators for general objectives. 	<ul style="list-style-type: none"> • Objective setting: set clear general and specific objectives; operational objectives only where possible and pertinent. • Repetition in detail of what will be presented in the explanatory memorandum.
"Narrow" legislative action	
<ul style="list-style-type: none"> • Detailed description of problems/ challenges (and their likely evolution) that necessitate EU legislation. • Short description of general objectives and detailed identification of specific and operational objectives. • Options as in minimum standards, if feasible; if range of options is limited by political constraints or previous policy, analyse different implementation modes or choices of instruments for preferred option. • Thorough analysis of impacts of all options in relevant pillar(s). • In case of a simplification initiative: clearly spell out the simplification benefits. • Always consider the impact on administrative burden (positive or negative). • Monitoring and evaluation arrangements to include indicators for general and specific objectives. 	<ul style="list-style-type: none"> • Assessment of impacts in relation to the objectives of wider EU-strategies/ other pillars, if the impact is clearly marginal. • Repetition in detail of what will be presented in the explanatory memorandum.

Expenditure programmes	
<ul style="list-style-type: none"> • Short description of change of problems/context that necessitates action and link with other EU policies or programmes. • In case of expiry/renewal use of monitoring and evaluation results. • Detailed identification of specific and operational objectives. • Thorough analysis of baseline option (no EU-policy or no change); assessment of options of alternative delivery mechanisms. • Assessment of impacts to focus on costs (quantitative) vs. benefits (qualitative or quantitative). • Concrete monitoring and evaluation provisions, including indicators reflecting specific and operational objectives. 	
Comitology items	
<ul style="list-style-type: none"> • Identification of specific and operational objectives, linked to the objectives/requirements of the basic legislation. • Options should include non-legislative action (short analysis of feasibility) and different implementation modes and/or technical detail of envisaged Commission decision (Consideration of whether "doing less" is possible). • Thorough assessment of impacts in relation to specific and operational objectives, taking full account of relevance of technical detail. • Monitoring and evaluation provisions should include concrete indicators reflecting specific and operational objectives. 	<ul style="list-style-type: none"> • Description of policy context/constraints and general objectives. • Assessment of impacts in relation to general objectives of basic legislation or wider EU-policies.

4. GATHERING INFORMATION FOR THE IA WORK

4.1 Data sources, collection and analysis

Good quality data – facts as well as figures – are an essential part of any impact assessment. You need them to define the problem and the baseline scenario, and to identify the impacts of alternative options for dealing with the problem. Particular attention needs to be paid to quality and credibility of data.

You should identify data needs at an early stage of the IA work. In many cases, the information you need for the IA will be available in the Commission, either in your own DG or in other services. This information may include monitoring or evaluation reports from previous or similar programmes, earlier impact assessments, studies carried out by or for the Commission, statistical data from Eurostat and others, studies and research by EU agencies, information gathered from stakeholders (hearings, conferences), results of consultation documents such as Green Papers, and so on. In other cases, you will also have to rely on data available at national or regional level in the Member States. You may need the support of Member States and/or stakeholders to identify and use these data, and you should solicit this support as early as possible. It may also be necessary to use external experts to gather data and undertake some of the analysis.

You should also look for examples of good practice in Member States, and at the experiences of third countries or international organisations. When the EU is involved in an international dialogue, or if there are internationally agreed standards, you should reflect this in the report.

4.2 Using external expertise

Impact Assessments can draw on work produced by consultants or external expertise, but must be drafted by the services of the Commission which remain fully responsible for the report.

Scientific and technical expertise is increasingly important in developing public policies. The Commission has produced guidelines for collecting and using such expertise.¹² Expert groups and, in particular, scientific committees set up by the Commission and EU Agencies are a prime source of scientific advice. In addition, since 2005, a web application called the SINAPSE e-Network¹³ (Scientific INformAtion for Policy Support in Europe) offers Commission services the following tools for the collection of expertise:

¹² COM (2002) 713. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0713:FIN:EN:PDF>

¹³ SINAPSE is accessible at <http://europa.eu.int/sinapse> (Contact: Sinapse@ec.europa.eu).

- A *library of scientific advice* and opinions;
- A *consultation* module which allows services to conduct informal scientific consultations, complementing formal advisory processes;
- An *early warning system* that the scientific community and other stakeholders can use as a channel for raising awareness on scientific issues which require or could benefit from the attention of public authorities;
- A '*Yellow Pages*' section to identify and contact quickly scientists or scientific organisations with a specific expertise.

NB: The lead service always remains responsible for the content and quality of the IA report. When you use external experts for parts of the IA, the terms of reference should make clear that contractors should follow the key analytical steps set out in chapter 5.

4.3 Consulting interested parties

Consulting interested parties is an obligation for every IA and it must follow minimum standards.

- **Plan your consultations early.**
- **Engage the right stakeholders, using the most appropriate timing, format and tools to reach them.**
- **When appropriate, maintain contact with stakeholders throughout the process.**
- **Analyse stakeholders' contributions for the decision-making process and give feedback in the IA report on how the input was used.**

Why consult?

Consulting those who will be affected by a new policy or initiative and those who will implement it is not only a Treaty obligation¹⁴ but also an indispensable tool for producing high quality and credible policy proposals. Consultation helps to ensure that proposed policies are workable, and it increases the legitimacy of EU action from the point of view of stakeholders and citizens.

When and what?

Depending on the objective pursued and the issue at stake, consultation can be carried out on different elements of the impact assessment (nature of the problem, objectives and policy options, impacts, comparison of policy options, assessment of costs and benefits).

Consultation is not a one-off event, but a dynamic process that may need several steps. It should be planned carefully and early both to maximise its usefulness and also to avoid 'consultation fatigue' through too many repeated consultations.

Planning should cover the whole policy-making process and include information on:

- the objective of the consultation(s): finding new ideas (brainstorming); collecting factual data; validating a hypothesis; etc;

¹⁴ See Protocol on the application of the principles of subsidiarity and proportionality.

- the elements of the IA for which consultation is necessary, e.g.: nature of the problem, objectives and policy options, impacts, comparison of policy options;
- the target groups: general public, a specific category of stakeholders or designated individuals / organisations;
- the appropriate consultation tool(s): consultative committees, expert groups, open hearings, *ad hoc* meetings, consultation via Internet, questionnaires, focus groups, seminars/workshops, etc.;
- the appropriate time for consultation(s): it should start early but can run at intervals throughout the IA process.

The consultation plan should be discussed with the IASG. There is no one-size-fits-all solution for stakeholder consultations, but there are minimum standards which must be applied.

Minimum consultation standards¹⁵

- Provide clear, concise consultation documents that include all necessary information.
- Consult all relevant target groups. Ask yourself who will be affected by the policy and who will be involved in its implementation?.
- Ensure sufficient publicity and choose tools adapted to the target groups - open public consultations must at least be publicised on the Commission's single access point for consultation, 'Your Voice in Europe'¹⁶.
- Leave sufficient time for participation (minimum eight weeks for written public consultations; 20 working days notice for a meeting).
- Publish the results of the public consultation on 'Your Voice in Europe'.
- Provide – collective or individual – acknowledgement of responses.
- Provide feedback: report on the consultation process, its main results and how you have taken the opinions expressed into account in the IA report (see chapter 2.3.) and in the explanatory memorandum accompanying the Commission proposal.

More information on these standards and on consultation of specific target groups is available in annex 4 and on the IntraComm site on stakeholder consultation¹⁷. You should note that there are specific provisions for consulting social partners on initiatives in the field of social policy based on articles 137-139 of the Treaty (see also annex 4).

Pitfalls

When carrying out the consultation and using the information it produces, you should be aware of a number of pitfalls that may introduce a bias into the results. It is important to distinguish evidence from opinions. Not all interest groups are equally able to take part in consultations or express their view with the same force. For this reason, an open consultation is unlikely to provide a fully representative picture of opinions. You should also be careful in drawing conclusions if there are only a small number of responses and they come from a narrow range of interests.

¹⁵ Cf. "Towards a reinforced culture of consultation and dialogue – General principles and minimum standards for consultation of interested parties by the Commission" (COM(2002) 704 final).

¹⁶ See http://ec.europa.eu/yourvoice/consultations/index_en.htm

¹⁷ See <http://www.cc.cec/home/dgserv/sg/stakeholder/index.cfm?lang=en&page=guidance>.

While you should be careful, however, not to be unduly influenced by the views of one particular group, no matter how professionally these have been presented, you should also give a response its due weight if it represents a large number of citizens or stakeholders¹⁸.

When you use a consultation to gather data, you should *verify* carefully that the method you use is correct and appropriate, and try to *validate* the robustness of the results. Peer-reviewing, benchmarking with other studies and sensitivity analysis can significantly enhance the quality of data. Consultation can never be a substitute for analysis of an issue¹⁹.

¹⁸ Also watch for biases that may arise in the context of on-line, closed-end questionnaires allowing for anonymous responses (e.g. the risk that a single person fills in the questionnaire many times).

¹⁹ See also annex 5 and the problem of 'regulatory capture'.

5. KEY ANALYTICAL STEPS IN IMPACT ASSESSMENT

Summary of key analytical steps

1. Identifying the problem

- > Describe the extent of the problem.
- > Identify the key players/affected populations.
- > Establish the causes.
- > Is the problem in the Union's remit to act? Does it pass the subsidiarity test?
- > Develop a clear baseline scenario, including, where necessary, sensitivity analysis and risk assessment.

2. Define the objectives

- > Set objectives that correspond to the problem and its root causes.
- > Establish objectives at a number of levels.
- > Ensure that the objectives are coherent with existing EU policies and strategies, such as the Lisbon and Sustainable Development Strategies, as well as the Commission's main priorities and proposals.

3. Develop main policy options

- > Identify policy options, where appropriate differentiated between options for delivery mechanisms (regulatory/non-regulatory approaches) and sub-options for modes of implementation (?)
- > Check the proportionality principle.
- > Begin to narrow the range through screening for technical and other constraints, and measuring against criteria of effectiveness, efficiency and consistency.
- > Draw-up a shortlist of potentially valid options for further analysis.

4. Analyse the impacts of the options

- > Identify (direct and indirect) economic, social and environmental impacts and how they occur.
- > Identify who is affected (including those outside the EU) and in what way.
- > Assess the impacts in qualitative, quantitative and monetary terms where possible and appropriate.
- > Identify administrative burden and simplification benefits, where relevant.
- > Consider the risks and uncertainties in the policy choices, including obstacles to compliance.

5. Compare the options

- > Weigh-up the positive and negative impacts for each option.
- > Where feasible, display aggregated and disaggregated results.
- > Present comparisons between options by area (???)
- > Identify, where possible and appropriate, a preferred option.

6. Outline policy monitoring and evaluation

- > Identify core progress indicators for the key objectives of the possible intervention.
- > Provide a broad outline of possible monitoring arrangements.
Provide a broad outline of possible evaluation arrangements.

5.1 What is the problem?

A good definition of the problem, and a clear understanding of its causes, are preconditions for setting objectives and identifying options to address the problem.

A good problem definition has to provide the following:

- It should *describe the problem in clear terms, relate it to the objectives of the EU, and support the description by clear evidence.*
- It should *set out clearly the scale of the problem* (how big is it?) and *who is most affected by it* (all citizens or groups of citizens? regions? economic sectors? natural resources? species?).
- It should *identify clearly the drivers or underlying causes* of the problem. Why does the problem exist? To what extent is this the result of a market failure or regulatory failure?
- It should describe *how the problem has developed over time and how existing policies* at Community or Member State level *affect the problem.*
- It should *identify a clear baseline*, i.e. it should describe how the problem is likely to develop in the future without new EU action. Assumptions made and risks involved must be clearly identified.
- It must clearly *describe why the problem needs action at Community level* on the basis of principles set in the Treaty (Conferral and Subsidiarity).

Uncertainty and risk in the baseline should be assessed properly

5.1.1 Defining the problem

The problem definition should describe in concrete terms the problem to be addressed. Annex 5 sets out some of the major reasons why public intervention may be necessary including market and regulatory failures. It should identify the drivers or underlying causes of the problem, and who is likely to be most affected. Only a precise problem definition will allow you to define your objectives and identify appropriate options for action.

Some years ago, statistics of country X revealed that a large number of children had died because of accidental poisoning in their homes caused by overdoses of medicines. Analysts quickly concluded that medicine bottles were too easy for children to open. Childproof bottles (with 'push down and turn' opening device requiring some physical strength) were then made compulsory. The trade-off was an increased difficulty for older persons to open their medicine bottles. As a result, these bottles were often left open, leading to more child poisonings.

Subsequent analysis showed that the main problem lay elsewhere: when packaging like sweets, medicines were very attractive for children; moreover, adults too often were leaving medicines easily accessible to children. Policy-makers eventually managed to tackle child poisoning through less colourful packaging integrating child warnings and an information campaign on the need to store medicines out of children's reach. Bottle caps were also redesigned so that people who can read can open them easily.

You should also identify the actors and groups that are primarily affected by the problem. In this context you should indicate which sectors, specific social groups or regions are most affected. Where the problem is not confined to the EU, you should also identify international aspects of the problem in this section.

Illustrating the incidence of the impacts associated with the problem.

It can be useful to include tables or maps in this chapter to give an overview of the social, sectoral or regional dimensions of the problem. This provides a first orientation for the subsequent analysis of impacts, and can already provide indications of where you might need a for better targeted consultation later on.

The problem definition chapter can also benefit from a simple, small-scale example of the essential aspects of the problem, for example in the context of a small business ('think small first').

As well as saying what the problem is, you should also explain why it is a problem, that is, why the existing or evolving situation is not sustainable, and public intervention will therefore be necessary. A useful tip is to consider the problem from the point of view of the different stakeholder groups affected. You need to establish the 'drivers' – or causes – behind the problem (how particular factors lead to the problem) and the ways in which these different drivers influence one another directly or indirectly. Doing so helps you to tackle root causes rather than symptoms. For example:

PROBLEMS	DRIVERS
Rapid spread of HIV/AIDS in country X	Stigma surrounding disease leads people to stop talking about it (culture of secrecy) and undermines preventive action
Air pollution	Firms do not bear the cost of pollution caused by their operations (market failure).
Firms unwilling to trade with countries X, Y, Z.	Protection of legal rights in these countries not adequately defined (regulatory failure).

Problems should not be defined as a 'lack of something', as this can bias the definition of objectives and the choice of policy instruments. For instance, stating that the problem of poverty and social exclusion in single parent households is the result of a lack of affordable childcare, which prevents single parents from working, will focus attention on provision of affordable childcare as a solution. By contrast, starting out by stating that single parents often have low skilled jobs and salaries on which they cannot afford childcare, opens up additional policy options (e.g. providing special training and educational opportunities for single parents, raising single parent salaries through fiscal measures, etc.).

Problem tree

A simple, but structured, approach to analysing problems and their root causes is to draw up a **problem tree** which maps out major problems and how they relate to each other. The output is a graphical arrangement of problems differentiated according to 'causes' and 'effects,' joined by a core, or focal, problem (see Annex 5.4.2).

5.1.2 Verifying the EU's right to act, and the justification for EU action (Conferral and Subsidiarity principles)

Once you have identified the problem and its underlying causes, the next step is to verify if the EU has the right to take action and if it is better placed than the Member States to tackle the problem.

You should link the problem to at least one article of the Treaties and the objectives it contains, as this is the basis for Union's right to act (**principle of conferral**). If the Community has exclusive competence in the area in question, the right to act is clear. In all other cases, the principles of subsidiarity and proportionality apply. You should also keep in mind from the outset that fundamental rights, as defined in the EU Charter of Fundamental Rights, may pose legal limits to the Union's right to take action on the problem.²⁰

Verifying the conferral of competence

- **Is the issue you are dealing with linked to at least one article of the Treaty, and the objectives it sets out?**
- **Is it an issue on which the Community has exclusive competence? If this is the case, then subsidiarity does not apply.**

The **subsidiarity principle** has two aspects which must both be met for Community action, legislative or non-legislative, to be justified.

- **Why can the objectives of the proposed action not be achieved sufficiently by Member States in the framework of their national constitutional system (*NECESSITY TEST*)?**
- **As a result of this, can objectives be better achieved by action by the Community (*TEST OF EU VALUE-ADDED*)?**

The following box contains the questions you should answer when examining whether the two aspects are met in your case. You should not answer them on a yes/no basis, but rather use them to identify the arguments relating to subsidiarity which are relevant in the context of your initiative so that you can elaborate them in your IA report. These points should be substantiated with qualitative, and where possible, quantitative indicators.

²⁰ The Commission has decided that proposals should be scrutinised for compatibility with the Charter of Fundamental Rights of the European Union. This is reflected in the table of questions in section 5.4.2. See also the Communication on Compliance with the Charter of Fundamental Rights in Commission legislative proposals (COM(2005) 172).

Respecting the subsidiarity principle

1. Does the issue being addressed have trans-national aspects which cannot be dealt with satisfactorily by action by Member States? (e.g. reduction of CO2 emissions in the atmosphere)
2. Would actions by Member States alone, or the lack of Community action, conflict with the requirements of the Treaty? (e.g. discriminatory treatment of a stakeholder group)
3. Would actions by Member States alone, or the lack of Community action, significantly damage the interests of Member States? (e.g. action restricting the free circulation of goods)
4. Would action at Community level produce clear benefits compared with action at the level of Member States by reason of its scale?
5. Would action at Community level produce clear benefits compared with action at the level of Member States by reason of its effectiveness?

In some cases, the answers to these questions may not be the same for each policy option that you examine. You should then answer the questions under each policy option.

An additional point should be borne in mind: any assessment of subsidiarity will evolve over time. This has two implications.

First, it means that Community action, in line with the provisions of the Treaty, may be expanded where circumstances so require. This may include areas where there has been no, or only limited, Community action before. Given the potential political sensitivity of such new activities, the clearest possible justification on the basis of the above guidelines is essential. Reference to similar activities already carried out at Community level may be useful.

Secondly, it not only means that Community action can be extended, it also means activities may be restricted or discontinued if they are no longer justified because circumstances have changed. It is important to bear this in mind when reviewing existing Community activities, for example in the context of the Commission's better regulation and simplification agenda. For this type of initiative, the IA report should demonstrate that EU action is still in conformity with the subsidiarity principle; you should not rely exclusively on a subsidiarity analysis that was made in the past.

The Treaty also requires that Community action meets the conditions set by the **principle of proportionality**. This should be examined as part of the assessment and comparison of policy options (see section 5.3.2.).

5.1.3 Developing a baseline scenario

**The problem definition must include
a clear baseline scenario
as the basis for comparing policy options**

The aim of the baseline scenario is to explain how the current situation would evolve without additional public intervention – it is the "no policy change" scenario.

The baseline scenario depends on whether or not there are already national and EU policies in place:

If there is no EU policy, the baseline means the continuation of "no EU policy".

Where there is already an EU policy, the baseline is the continuation of the current policy without any change, i.e. without any new or additional EU intervention.

If the existing EU policy foresees a change (e.g. abolition of the milk quota in 2015), or a sunset clause, then the baseline can over time lead to a "no EU policy" scenario

For these reasons it is important that you explain clearly the policy context of the initiative in an introductory chapter of the IA report.

To develop the 'no policy change' scenario, you will also need to consider a wide range of factors other than EU intervention; these include:

- Member State policies/regulations *already in place*;
- actions already decided or proposed by third countries, industries and other parties;
- evolution of relevant markets;
- recent trends in the problem and likely changes to the causes of those trends.

When you assess the impacts of the different policy options, you should present them as net changes compared to the baseline. Chapter 5.5 provides further information on how to do this.

A realistic baseline should have a strong factual basis and, as far as possible, be expressed in quantitative terms. It should also be set for an appropriate time horizon (neither too long nor too short). The baseline projection has to provide a clear indication of how serious the problem is, or to what extent it would become more serious without immediate intervention, and whether the consequences would be irreversible.

While the baseline should not include developments that depend on political decisions that have not yet been taken, there is one important exception to this: if the initiative is linked to other policy proposals already put forward by the Commission but not yet adopted by the legislator, these proposals may be assumed to be part of the baseline.

In describing the baseline scenario – as when assessing the impacts of any policy option – you may face the challenge that the the projections are uncertain or that there is a risk attached to them, i.e. that an undesired development may –or may not- happen. Sensitivity analysis and risk assessment are tools to respond to these challenges in your problem description.

5.1.4 Uncertainty and sensitivity analysis

When the assumptions underlying the baseline scenario may vary as a result of external factors, sensitivity analysis needs to be carried out to assess whether the impacts of the policy options differ significantly for different values of the key variables.

This analysis will have to address the impact of different assumptions on the effectiveness of policy options, and where necessary describe alternative versions of the baseline scenario.

Sensitivity analysis can be used to explore how the impacts of the options you are analysing would change in response to variations in key parameters and how they interact.²¹

The impact of your measure may be affected, for example, by changes in the rate of economic growth (x %) or the proportion (y %) of producers who adopt a voluntary standard. While these values are rarely known for sure, there is often a range of values that is more or less likely. Sensitivity analysis can be used to establish how variations in such parameters affect the impact of your measure. You should ask for help from the IA or economic analysis unit in your DG.

5.1.5 Risk Assessment

Every impact assessment that addresses a problem in which uncertainty is an issue should contain a risk assessment.

For serious risks that may involve irreversible damage or fatalities on an unforeseeable scale, a separate formal risk assessment will have to be carried out on the basis of scientific expertise.

Risk assessment and risk management

Decision-makers are constantly faced with the dilemma of balancing the freedoms and rights of individuals, industry and organisations with the need to reduce or eliminate the risk of adverse effects to the environment or to health. When the problem that the initiative deals with is connected with risk, i.e. there is uncertainty whether the negative developments will occur; the impact assessment will have to include a **risk assessment** as a tool to determine the best policy to deal with uncertain but potentially harmful consequences.

As a working definition you can equate the value of a given risk with the magnitude of the hazard, multiplied by the probability that it will occur. Especially when the hazard under consideration may have consequences that are not yet fully scientifically established, and that may be irreversible, a full risk assessment by a scientific committee is necessary.

In these cases, particularly when risks to the environment and human, animal and plant health are involved, the 'precautionary principle' may be applied as a first step towards

²¹ For useful techniques for sensitivity analysis see the book published by JRC: <http://sensitivity-analysis.jrc.cec.eu.int>

the **management of risk**.²² This means that decisions that might bring about the hazardous outcome are postponed until the necessary scientific assessment has been carried out. In the light of the risk assessment, Commission services should prepare, propose and carry out measures to manage the risk. Risk assessment and measures for risk management, though closely linked, should conceptually be kept apart when preparing an impact assessment.

How to carry out risk assessment in the context of impact assessment?

Risk assessment includes analysing the probability that a given undesired development will occur, exploring ways to reduce the risk, and possibly assessing mitigating measures. Regulatory intervention is often undertaken to reduce existing risks, such as a speed-limit that intends to reduce the likelihood and extent of road accidents. In these cases, it is necessary to analyse the risks to make informed policy choices on how to deal with them in an optimal way.

Three steps are necessary for risk analysis.

The first step is to **identify relevant risks**. You need to provide a clear description of the origin of the risk and the nature of the consequences it might have. The problem definition should set out under which circumstances who or what might be negatively affected and in what way.

The next step is to **determine the probability** that a negative consequence can occur and the **extent of the harm** that would materialise. Quantifying these two parameters should be attempted as far as possible to make risk analysis operational. All available scientific evidence should be used rather than subjective estimates. The extent of the harm can be difficult to measure in monetary terms, for example where harm relates to negative health or environmental impacts. Nevertheless, methods exist that can be used to monetise them (see annex 9).

Finally, you need to **describe alternative ways to reduce the identified risks** in the options section of the impact assessment report. The impacts on the risk need to be quantified so that you can compare the different costs of reducing the risk with the actual risk reduction. Risks can rarely be reduced to zero without incurring large costs. Risk analysis does not aim to eliminate risk at any cost but is rather a method to determine which measures can be used to reduce risks in an efficient way. Risks can be reduced either by limiting the extent of negative consequences when an event occurs, or by reducing the probability of such an event occurring, for example by limiting risky activities, or by a combination of both.

The results of the risk assessment should feed directly into the definition of objectives (i.e. whether the objective will be to eliminate or diminish the risk, or remedies like compensation will be pursued), and in the ways different policy options will deal accordingly with more detailed risk management. Annex 12.4 gives more technical detail on issues of risk analysis.

²² For more information on the precautionary principle and its use by decision-makers for the management of risk, see the "Communication from the Commission on the precautionary principle", COM (2000) 1.

5.2 What are the policy objectives?

Any Commission initiative must have *clear objectives* which are *directly related to solving the problems* which have been identified.

Only clearly defined objectives will make the level of ambition visible, show that the proposal respects the principles of subsidiarity and proportionality, help ensure coherence of Commission policies, and allow for identification and comparison of options for action and their likely impacts.

Without clear objectives, it is impossible to evaluate to what extent the action has generated its intended effects.

Defining objectives may be an iterative process where the objectives are refined in the course of the IA work. The definition should:

- Set out *objectives* that are *clearly linked to the problem and its root causes*, respect the subsidiarity and proportionality principles, and correspond to Treaty objectives and Commission priorities and strategies (such as the Lisbon and Sustainable Development Strategies);
- Set out *general objectives* and *translate them into specific* and, where appropriate, *operational objectives*, thus setting a hierarchy of objectives.
- Attempt to *express the objectives in SMART terms*:
(**S**pecific, **M**easurable, **A**chievable, **R**ealistic, **T**ime-dependent)

5.2.1 The role of objectives in an Impact Assessment

Without a clear understanding of what a future policy is supposed to achieve, it is difficult to identify possible courses of action, and even more difficult to compare policy alternatives. Objectives provide the only effective criteria for assessing the success or failure of the proposed policy options. Without clear objectives it is also impossible to monitor implementation of the policy and to evaluate whether it has produced the desired effects. Finally, setting objectives is a key step in determining the level of ambition of any policy and in linking it to existing Community policies (see chapter 5.2)

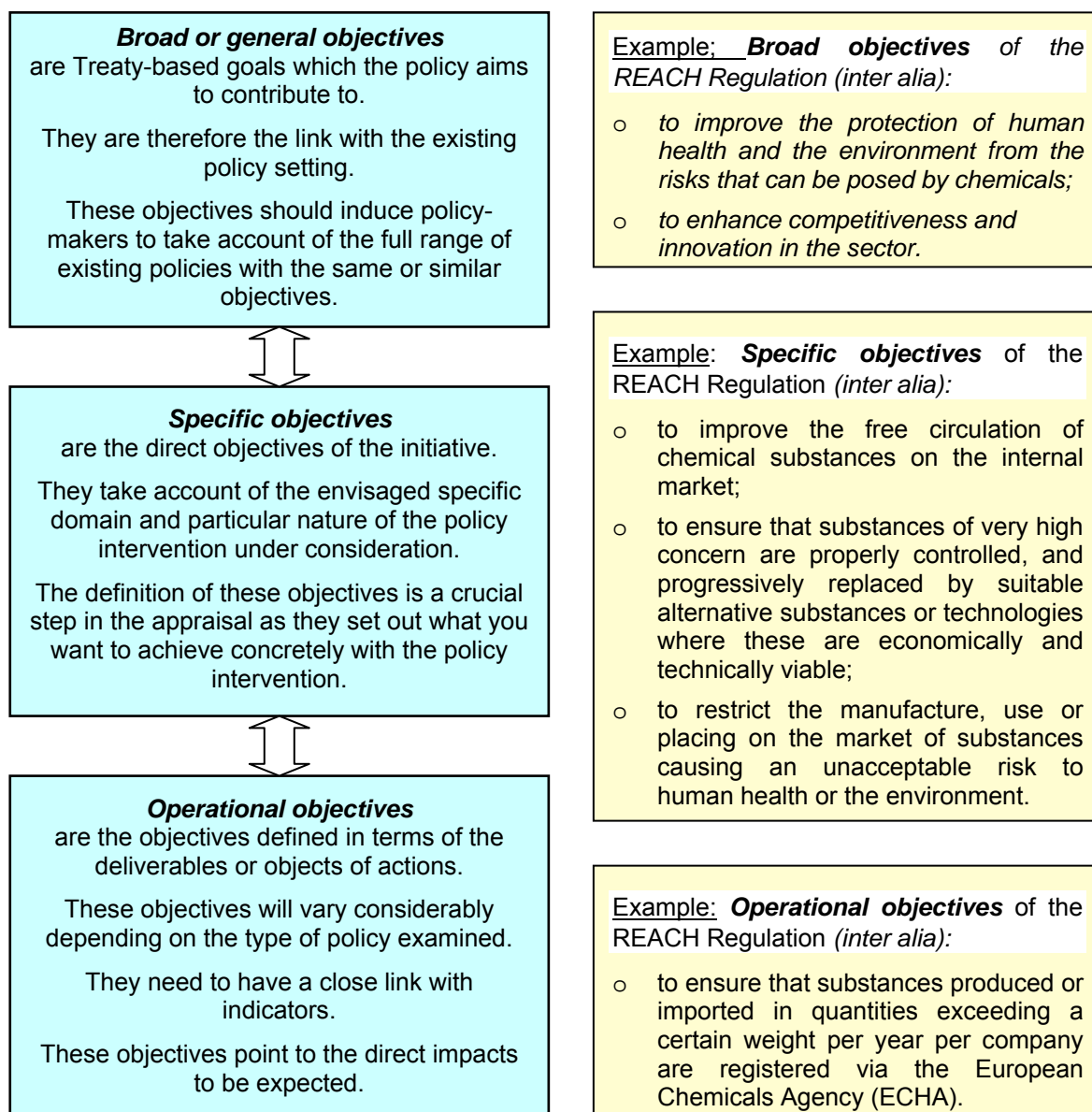
You should screen objectives at all levels on subsidiarity and proportionality aspects (see chapters 5.1.2. and 5.3.2).

5.2.2 Setting general, specific and operational objectives

To develop a coherent set of objectives, you should distinguish three levels: general objectives, specific objectives and operational objectives.

You will not always have to consider objectives on all three levels. For example, an IA accompanying a strategy or White Paper may not set out operational objectives. On the other hand, the IA of a comitology decision might focus on operational objectives, because general and specific objectives will already have been formulated in the IA for the legislation on which the comitology process is based.

When you define objectives at different levels, you should clarify the links between the objectives. There should always be a clear connection between your operational, specific and general objectives. Sometimes these relationships may not only be vertical (as in a hierarchy of objectives), but also horizontal, when objectives can reinforce but also contradict one another. You should also take account of any external factors outside your policy (and control) that may have favourable or adverse effects on your objectives.



5.2.3 When to set objectives?

Given that objectives are closely linked to the other stages of the IA process, you may not be able to define them in one go.

- Once you have defined the problem, you should be able to establish the broad policy objectives which the intervention aims to contribute to.
- The specific and operational objectives may change during the IA process as you gain more insight into the effectiveness and efficiency of various policy options. For example, as you work on a particular option you may encounter a drawback that you had not thought about before. It is then good practice to define a new (specific or operational) objective on avoiding this drawback. This ensures that the other options are also assessed on this aspect and consequently that the scoring and comparison of the options is carried out on the same set of criteria.

5.2.4 Linking objectives with other parts of the analysis

The objectives you set constitute the link between the problem description and the policy options that you will identify, assess and compare.

- Linking objectives with your problem analysis: Be sure that your objectives are directly related to the problem and its root causes.
- Linking objectives with the identification of policy options: this is an iterative process in which you revise your objectives and define more clearly your policy options: you cannot identify policy options without having a clear idea of the objectives, but equally you cannot lay down detailed objectives without taking into account the specificities of various policy options.
- Linking objectives with the assessment and comparison of policy options: The criteria that you should use when comparing the policy options are closely linked to the objectives. These criteria, "effectiveness", "efficiency" and "consistency", play a role already at the initial screening of "candidate" policy options. (For more information on the criteria see section 5.5.2.)
- Linking objectives with your future monitoring and evaluation activities: Without clear objectives you cannot monitor and evaluate whether your policy is on track. SMART objectives (see below) are needed to define good indicators. This in turn will allow you to monitor progress and evaluate the extent to which you have achieved your objectives.

5.2.5 Making your objectives SMART

Your objectives should be directly related to the problem and its root causes. Ideally they should be 'SMART'²³. It may not be possible to make every objective fully SMART, but you should aim to satisfy as many of the criteria as possible.

SMART-Objectives should be:

Specific: Objectives should be precise and concrete enough not to be open to varying interpretations. They must be understood similarly by all.

Measurable: Objectives should define a desired future state in measurable terms, so that it is possible to verify whether the objective has been achieved or not. Such objectives are either quantified or based on a combination of description and scoring scales.

Achievable: If objectives and target levels are to influence behavior, those who are responsible for them must be able to achieve them.

Realistic: Objectives and target levels should be ambitious - setting an objective that only reflects the current level of achievement is not useful - but they should also be realistic so that those responsible see them as meaningful.

Time-dependent: Objectives and target levels remain vague if they are not related to a fixed date or time period.

²³ These are explained in Article 27(3) of the Financial Regulation (Council Regulation N° 1605/2002).

5.3 What are the policy options?

Options must be clearly related to the objectives and must be proportionate.

In most cases, you should start by considering a wide range of options which is then narrowed down by screening them for technical and other constraints, and by assessing them against criteria of effectiveness, efficiency and coherence with other overarching EU policy objectives. Only the remaining options will then be analysed in depth. (Cf. "three-step approach of assessing impacts" in chapter 5.) You should always explain clearly the reasons for excluding options from an in-depth analysis.

Options analysed in depth must include the "no policy change" baseline scenario (see chapter 5.1.3); initial options should include the option of "no EU action" (if this is different from the baseline scenario and feasible) and the option of self- and co-regulation. In the case of regulation, where international standards exist, using these standards must be included as an initial option.

Options must be feasible and credible: you should avoid presenting only the status quo option, the "extreme" option and the preferred option.

Where relevant and possible, you should distinguish options at two levels:

- 1. options for the *intervention mode/regulatory technique* (Regulation, Directive, Recommendation, Communication, self-regulation, co-regulation) and**
- 2. options for the *content* of the intervention.**

You should define and analyse coherent 'packages' of options and sub-options.

In an IA for a legislative proposal, try to anticipate and assess in your options major amendments that Council and the European Parliament may introduce in the policy process.

5.3.1 Why consider alternative policy options?

Once you have defined the objectives, the next phase of the IA exercise is to establish which options and delivery mechanisms are most likely to achieve those objectives.

Considering a wide range of policy options will force you to think 'out of the box', and also provides greater transparency. It is a way to show policy-makers and stakeholders that alternative options that they may prefer have been analysed seriously, and to explain why they were not pursued. It becomes easier to explain the logic behind the proposed choices and to avoid unnecessary discussions of options that will not help to achieve the objectives.

Policy options must be closely linked both to the causes of the problem and to the objectives. You should define the appropriate level of ambition for the options in the light of constraints such as compliance costs or considerations of proportionality. You also need to identify the appropriate policy instrument (legal acts, legal acts of Member States, self-regulation, co-regulation and economic incentives). These instruments can of course be combined in a package, and/or co-ordinated with Member State action. Annex 6 provides further information on identifying options.

5.3.2 Respecting proportionality when defining options

The principle of proportionality states that any Community action should be as simple as possible while, of course, achieving satisfactorily the objectives which have been set. It is closely linked to the principle of subsidiarity discussed in section 5.1.2. Community action should be as simple as possible and leave as much scope for national decision as possible, and should respect well established national arrangements and legal systems. However, when defining options, you should also take aspects of transposition and compliance into account (see section 5.4.5).

The following questions should be used to examine the proportionality of the options proposed in an IA. They are not designed to be answered on a yes/no basis but rather should be explained and supported with qualitative and quantitative evidence where possible. Examining the proportionality of a range of options will help you to establish a shortlist of feasible options to be analysed in depth.

Applying the proportionality principle

Scope of instrument

1. Does the option go beyond what is necessary to achieve the objective satisfactorily?
2. Is the scope of action limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better? (boundary test):
 1. If the initiative creates a financial or administrative or administrative cost for the Union, national governments, regional or local authorities, economic operators and citizens, is this cost minimised and commensurate with the objective to be achieved?
 2. Will the Community action leave as much scope for national decision as possible?
 3. While respecting Community law, are well-established national arrangements and special circumstances applying in individual Member States respected?

Nature of instrument

1. Is the form of Community action (choice of instrument) as simple as possible, and coherent with satisfactory achievement of the objective and effective enforcement?
1. Is there a solid justification for the choice of instrument - regulation, (framework) directive, or alternative regulatory methods such as co-regulation or self-regulation?

5.3.3 How to identify and screen policy options

The first step is to think large and to draw up an extensive list of possible options that are likely to be able to achieve the proposed objectives. This initial list of options can then be reduced by a first screening of their likely impacts to arrive at a shorter list of options that is then analysed in depth (see also section 5.4.2)

All of your options should be realistic - you should avoid the trap of considering only the “no new action option”, the “preferred option”, and an “extreme option” which is not realistic.

Remember that you need to keep an open mind. Even if it seems that a particular option is a clear front-runner, other promising options should not be excluded outright.

The option of ‘**no new EU action**’ should always be considered, except in cases where the Treaties lay down a specific obligation to act. It is also necessary to consider, **alternative approaches to ‘classical’ forms of regulation**. Consideration should also be given to options leading to **streamlining or simplifying** existing regulation.

To regulate or not to regulate?

Tackling the problem does not mean that you need to choose a directive or a regulation. Consider the full range of alternative actions available to the Commission. Is self-regulation a feasible option? Could the same objectives be met by securing a voluntary agreement? Is an information and education campaign sufficient?

It is important to examine closely options that can count on considerable support. However, public and/or political support alone cannot be the sole determining factor in defining and analysing alternative options. When identifying the options you also need to take account of existing EU policies, including those that still have to be transposed by Member States, and if possible, relevant proposals which are still being discussed in the European Parliament and Council if you have not included them in the baseline. You should also take account of existing or planned Member State policies or international agreements that might affect the impact of an option.

‘Less can be more’

If there is already a body of legislation in place, a ‘doing less’ option could also be considered. If, for example, existing measures in a certain area do not produce the expected effects, creating a new instrument is not necessarily the best remedy. Streamlining, simplifying and ‘pruning’ the existing legislation might produce better results. Even abandoning EU intervention could be considered.

If a particular option emerges as a ‘front runner’ at a relatively early stage, you should also consider how the impacts of this ‘front runner’ will vary if one or more key parameters change (‘fine-tuning’), for example allowing more time for objectives to be met or aiming for more or less ambitious objectives. For this purpose you can use ‘sensitivity analysis’ (see chapter 5.1.4)²⁴.

It is important that options are ‘complete’, which means that they present fully developed ways of achieving the objectives. Individual elements that can be added to a credible and logical policy option should be presented and analysed as one option from the start. You should avoid ‘bundling’ individual elements/sub-options of different options into a ‘preferred’ option after the analysis, as this makes it difficult to assess the impact

²⁴ In the case of expenditure programmes, for example, a key design issue is the choice of the ‘method of implementation’: Will the programme be managed directly by the Commission, or indirectly through an Agency? Will management be shared with Member States or international institutions? (For more on the available options, see Article 53 of the Financial Regulation).

of the preferred option as a whole against the baseline. Where you do adopt this approach, you should carry out an analysis of this preferred option.

Options should of course be assessed against how well they meet the objectives. The options should be sufficiently well developed to allow you to differentiate them on the basis of how they are likely to perform against the criteria of effectiveness, efficiency and coherence with overarching EU objectives. Chapter 5.5 explains how to apply these criteria for assessing the impacts of options for screening and comparing them.

The aim of all interventions is of course to provide benefits that exceed any possible negative impacts. In the terminology of cost-benefit analysis this means that you should select options that promise the greatest net benefits.

5.4 What are the likely economic, social and environmental impacts?

Identify direct and indirect environmental, economic and social impacts and how they occur.

Identify who is affected by these impacts (including those outside the EU) and in what way.

Assess the impacts in qualitative, quantitative and monetary terms where possible and appropriate.

Consider the risks and uncertainties in the policy choices, including expected compliance patterns.

5.4.1 How to approach the analysis of impacts

In your analysis of impacts, you should address the likely economic, social and environmental impacts - both intended and unintended - for each option, as well as potential trade-offs and synergies.

The ultimate aim of this analysis is to provide clear information on the impacts of the various policy options as a basis for comparing them both against one other and against the status quo, and possibly for ranking the options in relation to clearly identified evaluation criteria (see chapter 5.5.4).

In presenting the impacts of different policy options it is essential to compare the options with the 'no policy change' option/baseline scenario (see chapter 5.1.3). You should show how each policy option differs from the baseline scenario, in terms of their characteristics and of the results that they would produce. The more quantification you can provide, the more convincing the analysis will generally be.

The IA should assess the estimated impacts of policy options as net changes compared to the baseline. Usually, this requires an inference from the collected data, either formally through statistical analysis or model runs, or more informally by drawing on an appropriate analogy with measured impact or activities. This assessment should go beyond the immediate and desired aspects (the direct effects) and take account of indirect effects such as side-effects, knock-on effects in other segments of the economy and crowding out or other offsetting effects in the relevant sector(s).

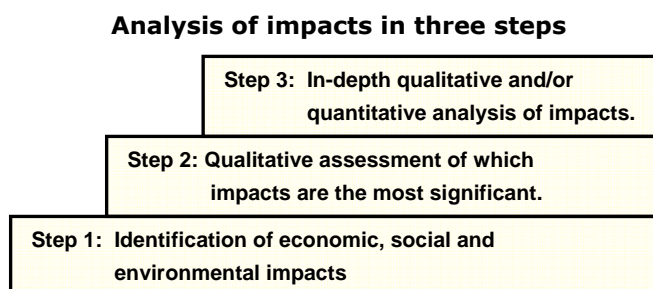
A variety of tools and models is available for assessing impacts and these are presented in Annex 11.1. The Commission has also developed a set of indicators to monitor the implementation of the EU sustainable development strategy²⁵. In assessing impacts it is recommended that you use these indicators if they are relevant for the proposal.

²⁵ SEC(2005) 161 final.

This will ensure that the impacts of different proposals can be compared and will promote coherence of individual proposals with the EU sustainable development strategy.

You should keep in mind that the credibility of an IA depends to a large extent on providing results that are based on reliable data and robust analysis, and which are transparent and understandable to non-specialists.

5.4.2 The three steps of impact analysis



The sources of information and data you need for the three steps will vary. You should be able to carry out steps 1 and 2 by drawing on expertise available in the Commission, desk reviews of existing research, studies and evaluations, possibly enriched by involving outside experts, and by utilising the results of consultations with stakeholders.

For the in-depth analysis of impacts (Step 3), you will most probably need to draw on the various information sources mentioned in chapter 4.

Step 1: Identify, economic, social and environmental impacts of a policy, why they occur and who is affected

The first step is to identify those impacts, both inside and outside the EU, that are likely to occur as a consequence of implementing the policy. Some impacts of the policy will be intentional and will have been identified in the form of objectives. However, it is also necessary to try to identify possible unintended impacts.

When identifying impacts you should state clearly the links between cause (the action, instrument, etc) and effects.

Tables 1 to 3 provide a useful basis on which to screen options against possible economic, social and environmental impacts. Certain questions also address issues of compatibility with the Charter of Fundamental Rights. These questions are not exhaustive, and should not be answered with a simple 'yes' or 'no'. They are meant to help you to develop your thinking on a wide range of potential impacts for the policy options. You may of course need to identify additional questions which are relevant to your area. The "Impacts inventory" of the IA Tools website may also be helpful.²⁶ This approach should result in a **comprehensive picture** of the potential effects of the policy option.

You should always identify clearly who is affected by the impacts. Options that would be beneficial for society as a whole may have positive and negative impacts that are spread unevenly across society. You should consider two distinct types of **distributional impacts**:

- Impacts on different social and economic groups: carefully identifying 'winners' and 'losers' can help you foresee obstacles to the proposed action and may point to the need to change its design, or to introduce accompanying measures to mitigate the negative impacts. For example, a proposal may be very beneficial for consumers, while the costs fall mainly on enterprises. There may also be important distributional effects even within a given group (e.g. between small and large companies, between

²⁶ See <http://iatools.jrc.ec.europa.eu> and annex 11.1.

market entrants and incumbents, between low-income and higher-income households, etc). Finally, the impacts may differ significantly between Member States or regions (see section 5.4.3)

- Impacts on existing inequalities. You should for instance compare regional, gender and minority impacts of the proposed action to see if it is likely to leave existing inequalities unchanged, aggravate them, or help to reduce them. This is not a simple matter: for example, differences between male and female lifestyles may mean that a proposal which appears to be neutral as regards gender equality will in practice have different impacts on men and women.

Table 1: Economic Impacts

ECONOMIC IMPACTS	KEY QUESTIONS
Functioning of the internal market	<ul style="list-style-type: none"> • Does the option have an impact (positive or negative) on the free movement of goods, services, capital and workers? • Will it lead to a reduction in consumer choice, higher prices due to less competition, the creation of barriers for new suppliers and service providers, the facilitation of anti-competitive behaviour or emergence of monopolies, market segmentation, etc?
Competitiveness, trade and investment flows	<ul style="list-style-type: none"> • Does the option have an impact on the competitive position of EU firms in comparison with their non-EU rivals? • Does it provoke cross-border investment flows (including relocation of economic activity)? • Are the proposed actions necessary to correct undesirable outcomes of market processes in European markets?
Impact on SMEs	<ul style="list-style-type: none"> • Does the option have disproportionate impacts (like compliance costs, necessary investment) on SMEs?
Operating costs and conduct of business	<ul style="list-style-type: none"> • Will it impose additional adjustment, compliance or transaction costs on businesses? • Does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)? • Does it affect access to finance? • Does it impact on the investment cycle? • Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited? • Will it entail stricter regulation of the conduct of a particular business? Will it directly lead to the closing down of businesses? • Are some products or businesses treated differently from others in a comparable situation?
Administrative burdens on businesses	<ul style="list-style-type: none"> • Does the option impose additional administrative requirements on businesses or increase administrative complexity? • Do these burdens weigh in relative terms heavily on SMEs (Small and Medium Enterprises)?
Property rights	<ul style="list-style-type: none"> • Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited? • Or will there be a complete loss of property?
Innovation and research	<ul style="list-style-type: none"> • Does the option stimulate or hinder research and development? • Does it facilitate the introduction and dissemination of new production methods, technologies and products? • Does it affect intellectual property rights (patents, trademarks, copyright, other know-how rights)? • Does it promote or limit academic or industrial research? • Does it promote greater resource efficiency?

ECONOMIC IMPACTS	KEY QUESTIONS
Consumers and households	<ul style="list-style-type: none"> • Does the option affect the prices consumers pay? • Does it impact on consumers' ability to benefit from the internal market? • Does it have an impact on the quality and availability of the goods/services they buy, and on consumer choice? (cf. in particular non-existing and incomplete markets – see Annex 2) • Does it affect consumer information and protection? • Does it have significant consequences for the financial situation of individuals / households, both immediately and in the long run? • Does it affect the economic protection of the family and of children?
Specific regions or sectors	<ul style="list-style-type: none"> • Does the option have significant effects on certain sectors? • Will it have a specific impact on certain regions, for instance in terms of jobs created or lost? • Does it have specific consequences for SMEs? • Is there a single Member State, region or sector which is disproportionately affected (so-called "outlier" impact)?
Third countries and international relations	<ul style="list-style-type: none"> • Does the option affect trade or investment flows between the EU and third countries? Does it affect EU trade policy and its international obligations, including in the WTO? • Does the option affect specific groups (foreign and domestic businesses and consumers)? • Does the option concern an area in which international standards, common regulatory approaches or international regulatory dialogues exist? • Does it affect EU foreign policy and EU/EC development policy? • Does the option affect third countries with which the EU has preferential trade arrangements? • Does it affect developing countries at different stages of development (least developed and other low-income and middle income countries) in a different manner? • Does the option impose adjustment costs on developing countries? • Does the option affect goods or services that are produced or consumed by developing countries?
Public authorities	<ul style="list-style-type: none"> • Does the option have budgetary consequences for public authorities at different levels of government, both immediately and in the long run? • Does the option require significant establishing new or restructuring existing public authorities?
The macroeconomic environment	<ul style="list-style-type: none"> • Does it have overall consequences of the option for economic growth and employment? • Does it contribute to improving the conditions for investment and for the proper functioning of markets? • Does the option have direct or indirect inflationary consequences?

Table 2: Social Impacts

SOCIAL IMPACTS	KEY QUESTIONS
Employment and labour markets	<ul style="list-style-type: none"> • Does the option facilitate new job creation? • Does it lead directly to a loss of jobs? • Does it have specific negative consequences for particular professions, groups of workers, or self-employed persons? • Does it affect the demand for labour? • Does it have an impact on the functioning of the labour market?
Standards and rights related to job quality	<ul style="list-style-type: none"> • Does the option impact on job quality? • Does the option affect the access of workers or job-seekers to vocational or continuous training? • Will it affect workers' health, safety and dignity? • Does the option directly or indirectly affect workers' existing rights and obligations, in particular as regards information and consultation within their undertaking and protection against dismissal? • Does it affect the protection of young people at work? • Does it directly or indirectly affect employers' existing rights and obligations? • Does it bring about minimum employment standards across the EU? • Does the option facilitate or restrict restructuring, adaptation to change and the use of technological innovations in the workplace?
Social inclusion and protection of particular groups	<ul style="list-style-type: none"> • Does the option affect access to the labour market or transitions into/out of the labour market? • Does it lead directly or indirectly to greater in/equality? • Does it affect equal access to services and goods? • Does it affect access to placement services or to services of general economic interest? • Does the option make the public better informed about a particular issue? • Does the option affect specific groups of individuals, firms, localities, the most vulnerable, the most at risk of poverty, more than others? • Does the option significantly affect third country nationals, children, women, disabled people, the unemployed, the elderly, political parties or civic organisations, churches, religious and non-confessional organisations, or ethnic, linguistic and religious minorities, asylum seekers?
Equality of treatment and opportunities, non - discrimination	<ul style="list-style-type: none"> • Does the option affect equal treatment and equal opportunities for all? • Does the option have a different impact on women and men? • Does the option promote equality between women and men? • Does the option entail any different treatment of groups or individuals directly on grounds of sex, racial or ethnic origin, religion or belief, disability, age, and sexual orientation? Or could it lead to indirect discrimination?
Private and family life, personal data	<ul style="list-style-type: none"> • Does the option affect the privacy of individuals (including their home and communications) or their right to move freely within the EU? • Does it affect family life or the legal, economic or social protection of the family? • Does the option involve the processing of personal data or the concerned individual's right of access to personal data?
Governance, participation, good administration, access to justice, media and ethics	<ul style="list-style-type: none"> • Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach? • Are all actors and stakeholders treated on an equal footing, with due respect for their diversity? Does the option impact on cultural and linguistic diversity?

SOCIAL IMPACTS	KEY QUESTIONS
	<ul style="list-style-type: none"> • Does it affect the autonomy of the social partners in the areas for which they are competent? Does it, for example, affect the right of collective bargaining at any level or the right to take collective action? • Does the implementation of the proposed measures affect public institutions and administrations, for example in regard to their responsibilities? • Will the option affect the individual's rights and relations with the public administration? • Does it affect the individual's access to justice? • Does the option make the public better informed about a particular issue? Does it affect the public's access to information? • Does the option affect the media, media pluralism and freedom of expression? • Does the option raise (bio) ethical issues (cloning, use of human body or its parts for financial gain, genetic research/testing; use of genetic information)?
Public health and safety	<ul style="list-style-type: none"> • Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (working environment, income, education, occupation, nutrition)? • Does the option increase or decrease the likelihood of bioterrorism? • Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment? • Does it affect health due to changes in the amount of noise or air, water or soil quality in populated areas? • Will it affect health due to changes energy use and/or waste disposal? • Does the option affect lifestyle-related determinants of health such as use of tobacco, alcohol, or physical activity? • Are there specific effects on particular risk groups (determined by age, gender, disability, social group, mobility, region, etc.)?
Crime, Terrorism and Security	<ul style="list-style-type: none"> • Does the option improve or hinder security, crime or terrorism? • Does the option affect the criminal's chances of detection or his/her potential gain from the crime? • Is the option likely to increase the number of criminal acts? • Does it affect law enforcement capacity? • Will it have an impact on the balance between security interests and the rights of suspects? • Does it affect the rights of victims of crime and witnesses?
Access to and effects on social protection, health and educational systems	<ul style="list-style-type: none"> • Does the option have an impact on services in terms of their quality and access to them? • Does it have an effect on the education and mobility of workers (health, education, etc.)? • Does the option affect the access of individuals to public/private education or vocational and continuing training? • Does it affect the cross-border provision of services, referrals across borders and co-operation in border regions? • Does the option affect the financing / organisation / access to social, health and education systems (including vocational training)? • Does it affect universities and academic freedom / self-governance?

Social impacts in third countries	<ul style="list-style-type: none"> • Does the option have a social impact on third countries that would be relevant for overarching EU policies, such as development policy? • Does it affect international obligations of the EU arising from e.g. the Partnership Agreement ACP-EC or the Millennium Development Goals? • Does it increase poverty in developing countries or have an impact on income of the poorest populations?
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Table 3: Environmental impacts

ENVIRONMENTAL IMPACTS	KEY QUESTIONS
Air quality	<ul style="list-style-type: none"> • Does the option have an effect on emissions of acidifying, eutrophying, photochemical or harmful air pollutants that might affect human health, damage crops or buildings or lead to deterioration in the environment (polluted soil or rivers etc)?
Water quality and resources	<ul style="list-style-type: none"> • Does the option decrease or increase the quality or quantity of freshwater and groundwater? • Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)? • Does it affect drinking water resources?
Soil quality or resources	<ul style="list-style-type: none"> • Does the option affect the acidification, contamination or salinity of soil, and soil erosion rates? • Does it lead to loss of available soil (e.g. through building or construction works) or increase the amount of usable soil (e.g. through land decontamination)?
The climate	<ul style="list-style-type: none"> • Does the option affect the emission of ozone-depleting substances (CFCs, HCFCs, etc.) and greenhouse gases (e.g. carbon dioxide, methane etc) into the atmosphere?
Renewable or non-renewable resources	<ul style="list-style-type: none"> • Does the option affect the use of renewable resources (freshwater, fish) more quickly than they can regenerate? • Does it reduce or increase use of non-renewable resources (groundwater, minerals etc)?
Biodiversity, flora, fauna and landscapes	<ul style="list-style-type: none"> • Does the option reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)? • Does it affect protected or endangered species or their habitats or ecologically sensitive areas? • Does it split the landscape into smaller areas or in other ways affect migration routes, ecological corridors or buffer zones? • Does the option affect the scenic value of protected landscape?
Land use	<ul style="list-style-type: none"> • Does the option have the effect of bringing new areas of land ('greenfields') into use for the first time? • Does it affect land designated as sensitive for ecological reasons? Does it lead to a change in land use (for example, the divide between rural and urban, or change in type of agriculture)?
Waste production / generation / recycling	<ul style="list-style-type: none"> • Does the option affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of or recycled?
The likelihood or scale of environmental risks	<ul style="list-style-type: none"> • Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents and accidental emissions? • Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms? • Does it increase or decrease the likelihood of natural disasters?

Mobility (transport modes) and the use of energy	<ul style="list-style-type: none"> • Does the option increase or decrease consumption of energy and production of heat? • Will it increase or decrease the demand for transport (passenger or freight), or influence its modal split? • Does it increase or decrease vehicle emissions?
The environmental consequences of firms' activities	<ul style="list-style-type: none"> • Does the option lead to changes in natural resource inputs required per output? Will it lead to production becoming more or less energy intensive? • Does the option make environmentally un/friendly goods and services cheaper or more expensive through changes in taxation, certification, product, design rules, procurement rules etc.? • Does the option promote or restrict environmentally un/friendly goods and services through changes in the rules on capital investments, loans, insurance services etc? • Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?
Animal and plant health, food and feed safety	<ul style="list-style-type: none"> • Does the option have an impact on health of animals and plants? • Does the option affect animal welfare (i.e. humane treatment of animals)? • Does the option affect the safety of food and feed?
International environmental impacts	<ul style="list-style-type: none"> • Does the option have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy?

Step 2: Identifying the most important impacts

Simple tools are available to help you to identify the most important impacts. The causal model described in Annex 5.4 provides a basis on which you can build a more sophisticated analysis if the significance and nature of the proposal requires it (cf. the principle of proportionate analysis).

You may also use a qualitative assessment. In this approach, you will have to:

- Assign likelihoods (e.g. low, medium or high probability) that the impact will occur (or conversely the risk that the impact will not occur). This can be done by setting out your assumptions about factors that may influence the probability that impacts will occur, but which are outside the control of those managing the intervention.
- Assess the magnitude of each impact (e.g. low, medium or high). This can be done by considering the influence of the intervention on the behaviour of addressees and vis-à-vis the socio-economic and environmental context in which the intervention takes place. Ask yourself whether some of the impacts could be irreversible (See also Annex 12.5 on the precautionary principle).
- Assess the importance of impacts on the basis of the two preceding elements (e.g. from low likelihood/low magnitude through to high likelihood/high impact).

The impacts of regulatory instruments and spending programmes will depend in part on whether they are actually implemented and not just how they are implemented. The extent to which compliance is likely should be considered as a likelihood/risk of an impact occurring. For more information on the assessment of transposition and compliance, see chapter 5.4.5 below.

A third approach to assessing impacts is to build an '**impact matrix**'. It involves the following five tasks:

- 1. Break the policy options down into their main actions (the rows of the matrix).**
- 2. Identify the main types or categories of impacts (the columns of the matrix), organised according to a time horizon where possible.**
- 3. Indicate in each cell the likelihood of an impact (certain, probable, unlikely).**
- 4. Indicate in each cell whether the impact is expected to be positive or negative, or uncertain. Where it is positive or negative the magnitude can also be indicated.**
- 5. Indicate in each cell the addressees (or affected populations), the timescale over which the impacts are expected to occur.**

Whichever approach you use for identifying impacts, you should keep the following points in mind:

- 1. Given the potential complexity of the analysis, it is important that it is done in a structured and explicit way, both for communicating results and to provide a basis for further, in-depth analysis.**
- 2. Consider both short-term and long-term impacts: it is often easier to identify short-term effects, but this does not mean that they are more important.**
- 3. Do not overlook impacts that cannot readily be expressed in quantitative or monetary terms.**
- 4. Remember that different factors influencing impacts interact with one another.**
- 5. Take account of how the impacts of the proposal may be affected by the implementation of other proposals, particularly if the proposal is part of a 'package'.**
- 6. Impacts should be considered in the context of Treaty objectives and the EU's overarching policy goals, such as promoting sustainable development, achieving the goals of the Lisbon Strategy, the EU energy strategy, and respect for Fundamental Rights**

Step 3: In-depth analysis of impacts

After carrying out a structured, qualitative analysis of a proposal's impacts, further in-depth analyses, when considered proportionate, can again take a number of forms, building on the analysis and results of Step 2:

- In-depth qualitative analysis of selected impacts typically uses a case study/scenario approach. This type of analysis can be implemented on its own, though in reality it is generally used in conjunction with a quantitative analysis of impacts.
- Quantitative analysis of impacts: the selected impacts are estimated using quantitative techniques, varying from simple extrapolation - based for instance on previously derived coefficients (e.g. units of CO₂ per unit of industrial activity) - through to proper quantitative modelling. Essentially, the aim is to understand the extent of the impacts of the policy options and to estimate the costs and benefits in monetary form when this is feasible. Annexes 11 and 12 provide further guidance on how to undertake a quantitative analysis and set out some important rules for economic analysis²⁷

²⁷ You should use the standard discount rate of 4% (see Annex 11.4 on discounting)

5.4.3 Further guidance for assessing specific aspects of economic, social and environmental impacts

This section provides summaries of further guidance that was developed for assessing specific or sectoral aspects of economic, social and environmental impacts. This information is presented more fully in the annexes 7, 8 and 9 and on related websites.

Assessing impacts specifically affecting SMEs: given that they are small, SMEs can be affected by the costs of regulations more than their bigger competitors. At the same time, the benefits of regulations tend to be more evenly distributed over companies of different sizes. The IA should analyse whether this is the case for the options²⁸.

SMEs may have limited scope for benefiting from economies of scale. For example, if a new regulation requires them to buy equipment, that equipment could be relatively more expensive for SMEs than for their bigger competitors, given that they might make less use of it, or have lower levels of production or a lower number of employees.

Furthermore, SMEs in general find it more difficult to access capital and as a result the cost of capital for them is often higher than for larger businesses. This makes investments more expensive. SMEs are also more constrained in passing on increases in costs to their customers as they often have little direct influence on market prices.

Lastly, indirect costs can also have a greater impact on SMEs than on large businesses. For example, to comply with new obligations SMEs might need to employ external expertise or to invest in extra training of staff. Possible changes in the market structure could also particularly affect the competitiveness of SMEs and even put them out of the business.

When the analysis shows that SMEs are disproportionately affected or disadvantaged compared to large companies, you should consider using possible mitigating measures. Annex 7.5 provides further guidance on assessing impacts on SMEs and on possible mitigation measures.

Assessing social impacts: a "Toolkit" is available on the Impact Assessment Website.²⁹ It provides guidance on potential impacts in the areas of: (i) Employment and labour market; (ii) Standards and rights related to job quality; (iii) Social inclusion and protection of particular groups; (iv) Equality of treatment and opportunities, non – discrimination, and (v) Access to and effects on social protection, health and educational systems. An overview of statistics and available information, both internal and external to the Commission, as well as a quick review of available models and the most relevant recent studies is provided. For each of the selected areas, a quick description of the EU policy and legal framework, and the main potential effects to be explored is also described.

²⁸ See the report of the expert group "Models to reduce the disproportional regulatory burden on SMEs" (http://ec.europa.eu/enterprise/entrepreneurship/support_measures/regmod/index.htm).

²⁹ Cf. the "Sectoral Tools" website on the IntraComm Impact Assessment Website; http://www.cc.cec/home/dgserv/sq/i/impact/sector_tools_en.htm

Assessing consumer impacts: a handbook (based on the consumer detriment methodology) is available on the Impact Assessment Website³⁰. Annex 4.3 provides additional guidance on how to take account of consumer impacts.

Assessing impacts on competition in the internal market:³¹ competition helps companies to grow by outperforming one another and by improving their offer to consumers. Competition at the same time helps them to remain competitive on a European and global scale. Proposals may have an influence on the way companies compete against each other. To screen the proposal for possible negative impacts on competition, you should start by determining in particular if the proposal includes:

- Rules on liberalisation (of formerly monopolised network utilities such as electricity, telecoms, postal sector, public transport, etc.) and internal market measures;
- Measures raising or lowering the barriers to entry or exit, making it harder or easier for firms to enter or leave the market;
- Rules introducing special commercial rights (e.g. IPRs) or exempting certain activities from the application of the competition rules;
- Sectoral rules pursuing economic, environmental or regional policy goals;
- General rules (e.g. corporate law) governing economic activity

If so, you should assess whether the proposal contains rules which:

- (partially) exempt a market/sector from the application of the competition rules, thus possibly creating/strengthening a monopoly? (e.g. the defence sector or certain agricultural products).
- directly interfere with the way firms market or price their products/services, does it limit or reserve distribution for certain channels/ intermediaries, thus reducing consumer choice or creating barriers for newcomers? (e.g. advertising or marketing restrictions, rules on prices/ quality standards).
- facilitate or induce companies to agree on prices or divide up customers/markets, thus driving up consumer prices or decreasing innovative activity? (e.g. certain market organizations for agricultural products).
- restrict access to important resources (such as raw materials, land, IPRs, know-how or process technology) in concentrated markets, thus excluding or delaying market entry of alternative products/services? (e.g. in new media or IT sectors, or in the pharmaceutical sector).
- (de facto) favour incumbent providers at the expense of new entrants thus mitigating the beneficial effects of liberalisation? (e.g. depriving consumers of benefits such as increased choice or more competitive prices in the telecoms, energy, or transport sectors).

³⁰ *Ibid.*

³¹ For consideration of competition impacts you should consult the additional guidance prepared by DG COMP and available via the IA website at http://www.cc.cec/home/dgserv/sg/i/impact/index_en.htm.

Assessing impacts at national and regional level: while your impact assessment will typically examine problems that can be addressed by action at EU-level, the problem may have specific relevance for certain Member States, groups of Member States (such as new or smaller Member States, Mediterranean/Nordic MS), or regions. The options that are developed to tackle the problem may also affect different parts of the EU in very different ways³².

The IA should take these disaggregated effects into account. Policy options should be assessed for the possibility that impacts, positive or negative, will be spread unevenly. When a single Member State or region is disproportionately affected (so-called “outlier” impact), this should be mentioned. Where such disparities appear to be significant, they should be analysed as they may be a reason to adapt the initiative, for instance to offer mitigating or transitional measures for the “outlier”. This may in some cases justify a further quantification and monetisation of costs and benefits for specific regions.

If you need additional information on these impacts, you might organise targeted consultations for the relevant stakeholders and affected parties in such regions. The Committee of the Regions may be able to provide assistance in these cases.

Assessing international impacts: every impact assessment should establish whether proposed policy options have an impact on relations with third countries. In particular they should look at:

- The competitiveness of European businesses: the impacts of the policy should be analysed to see how the objectives can be achieved while avoiding or minimising potential negative impacts on European competitiveness. This should include an analysis of similar regulations which already exist in the EU's main trading partners.
- Trade relations with third countries: some policies may affect trade or investment flows between the EU and third countries; the IA should analyse how different groups (foreign and domestic businesses and consumers) are affected by such a proposal, and help to identify options which do not create unnecessary barriers.
- Impacts on developing countries: initiatives that may affect developing countries should be analysed for their coherence with EU commitments on development policy. This includes an analysis of consequences (or spill-overs) in the longer run in areas such as environmental, social or security policy.

You should already identify in the problem definition whether international aspects are relevant and need to be analysed. You should refer where relevant to existing bilateral dialogues, agreements, or standards, e.g. the regular EU-US regulatory dialogue. The policy options and impacts sections should analyse in greater detail what the specific impacts may be, how undesired effects can be avoided or minimised, how the options compare in this respect and what trade-offs have to be addressed in the final policy choice. The IA report has to reflect how and to what extent the evaluation of international impacts has been taken into account in the comparison of options.

To ensure that these aspects are dealt with appropriately in the IA, it is essential that you involve the services responsible for the relevant international aspects in the IASG. Their representatives can also help to ensure that stakeholders in third countries participate in the consultation process. Existing international policy dialogues can also be used to keep third countries fully informed of forthcoming initiatives, and as a means of exchanging information, data and results of preparatory studies with partner countries and other external stakeholders.

³² You should thereby also take account of impacts in relation to Treaty objectives such as (economic) convergence etc.

5.4.4 Assessing administrative burdens and simplification potential

For all policy options, the IA should provide an overview of information obligations for businesses, for citizens and national/regional/local administrations, that are likely to be added (or eliminated) if the option were implemented.

In those cases in which the change in administrative burden is likely to be significant, the effects should be assessed quantitatively using the EU Standard Cost Model.

The assessment of (positive or negative) effects on administrative burden on businesses, citizens or public administrations resulting from EU legislation should begin with a full mapping of information obligations for each of the options. This mapping can be based on a qualitative assessment and should show clearly how policy options differ in terms of information obligations. When this assessment indicates that the administrative burden created by information obligations may be significant, they should be estimated using the EU Standard Cost Model. In cases where the reduction of the administrative burden is an explicit objective, the effects should also be quantified using the EU Standard Cost Model.

For policy options that entail new information obligations, you should indicate in the IA how this information contributes to the effectiveness of the option in achieving the objectives. You should always consider alternative options that do not lead to additional information obligations. It is important that the analysis of the impacts clarifies the trade-offs between information obligations and the principal objectives of the proposal.

Annex 10 provides further Guidance on assessing administrative burden using the EU Standard Cost Model.

If simplification of existing legislation is one of the objectives of the proposal, the IA should provide an overview for all policy options of the potential simplification benefits for businesses, for citizens, and for national/regional/local administrations. In those cases in which simplification benefits are likely to be significant, the potential cost savings should be assessed quantitatively.

All proposed policy options should be assessed for coherence with the Better Regulation objective that EU legislation should be made simpler and more transparent. For proposals which are included in the Rolling Programme for simplification, and for which an IA is carried out, the IA should provide a qualitative description and where possible a quantitative estimate of the simplification benefits for businesses, citizens and national, regional or local administrations. The relevant entry in the Rolling Programme will generally already indicate what aspects of the existing legislation need to be simplified. The IA analysis should specify the extent to which each of the policy options achieves this simplification, and the difference that this will make in practice.

When a piece of legislation is being simplified and at the same time updated with new rules, you should analyse the simplification aspects and the new elements separately, and then assess the aggregate effect.

5.4.5 Assessment of transposition and compliance aspects

The Treaty requires that any action should be as simple as possible and leave as much scope for national decision as possible. Impact assessments must therefore deal with issues of implementation, management and enforcement. "Maximum effort should be made to ensure the clarity, simplicity, operability and enforceability of legislation."³³

When you consider compliance issues, you need to remember that EU rules are in general implemented by Member State authorities. Your compliance analysis therefore needs to take account of possible variations in how Member States implement the rule. For example, framework directives leave considerable scope for flexible implementation at Member State level. This could have a knock-on effect on compliance by the target groups in different countries. In the case of Directives, it is important to be aware of national difficulties in implementing certain requirements. This should be taken into account when setting implementation periods. Consulting the target population and the Member States will help you in your compliance analysis.

The following questions will help you to identify potential obstacles to compliance by the group whose behaviour is meant to change, and any incentives that might increase compliance:

Identifying potential obstacles and incentives to compliance

Are the requirements of the options simple and easy to understand?

Inaccessible and incomprehensible rules will reduce compliance, particularly for small businesses, which often lack time and resources to deal with large volumes of complex rules.

Would the target group be able and willing to comply? This may depend on the following:

- **Compliance costs**, including administrative burdens, may affect overall compliance rates, in particular those of disproportionately affected groups such as small businesses.
- **Overly complicated and technical regulation** may not be properly understood. Moreover, it may appear not to have any clear purpose, leading to a loss of confidence in the regulators and a tendency to evasive behaviour.
- **Coherence** with existing market practices or cultural norms may help raise compliance rates.
- **Prior consultation** builds in a sense of 'ownership', or at least understanding, of the rule and can ease compliance concerns.
- **Rigorous monitoring arrangements and sanctions for non-compliance** can be expected to increase compliance rates.
- **Providing information and other support measures** can affect the ability of the target group to comply with the rule.

³³ Cf. Commission Communication "A Europe of results – applying Community law", COM (2007)502 final.

5.5 How do the options compare?

Use the following criteria for the comparison of options, and explain how they have been applied:

- 1. Effectiveness of the option in relation to the set objectives**
- 2. Efficiency of the option in achieving the objectives**
- 3. Coherence of the option with overarching EU objectives, strategies and priorities**

Compare the options against the baseline scenario.

Present for all options analysed in detail a summary overview of *all positive and negative economic, social, and environmental impacts.*

5.5.1 How to present the compared impacts of different options

Regardless of the way you choose to present the impacts, it must be clear that

all these qualitative assessments are based on evidence, including quantitative data.

The reasoning that leads from the evidence to the assessments in these tables has to be fully transparent.

For all of the options you analyse (including the 'no EU action' option), you need to consider all the relevant **positive** and **negative** impacts alongside each other, regardless of whether they are expressed in qualitative, quantitative or monetary terms. Annex 12 presents three methods for comparing options (cost-benefit analysis, cost-effectiveness analysis, and multi-criteria analysis).

The approach presented here is a simple multi-criteria analysis which compares positive and negative impacts expressed in qualitative, quantitative and monetary terms.

As a first step, you should summarize the impacts of each option by area of impact (economic, social, environmental) and even by sub-impacts. In this summary, the impacts should not be aggregated; negative and positive impacts should be stated next to each other. In some cases, it may be possible to assess net impacts per area of impact and potentially to provide an assessment of the overall net impact (positive impact minus negative impact) of each option. However, when this type of cumulative presentation of impacts is made, you should be careful not to give the impression that impacts are zero or low when, in fact, it is a case of significant positive and negative impacts of the same type having simply cancelled each other out.

An example of good practice in presenting results for each option can be seen in table 1, which breaks down the economic, social and environmental impacts into individual impacts, described in qualitative, quantitative and monetary terms as appropriate. This makes clear what is and is not included in the aggregated data, and is therefore more transparent than only providing a single overall monetised value. A further example of good practice is to summarise the impacts of all policy options side by side

Table 1

	Qualitative Description	Quantitative Description	Monetised Value
Economic Impacts			
Costs to Enterprises sub-impacts	<i>Obligation to install new air pollution equipment</i>	<i>Approx. 400 firms affected</i>	<i>€ 400 million</i>
Social Impacts			
Communities sub-impacts	<i>Better quality of life in communities</i>	<i>Around 100 benefiting (near to firms)</i>	<i>Not monetised</i>
Environmental Impacts			
Air pollution sub-impacts	<i>Reduced mortality rates</i>	<i>'X' premature deaths avoided each year</i>	<i>€ Y billion (value of 1 life multiplied by 'X')³⁴</i>

In table 2 taken from the Impact Assessment on the Visa Information System (VIS)³⁵, the costs and benefits of each of the options have been set out in an easily understandable way. Annex 12.3 provides further examples of how to present the comparison of impacts.

Table 2

Costs	Financial costs	Opportunity costs for visa applicants	Retaliation costs for EU travellers	Reductions in business travel and tourism	Impact on fundamental rights, in particular the protection of personal data and privacy
No VIS	-	-	-	-	-
Entry-exit system	√√√√	√√	√	√	√√√√
VIS without biometrics	√	-	-	-	√√
VIS with biometrics	√√	√√	√	√	√√√

³⁴ While it is possible to monetise the statistical value of human life in economic terms, this approach should always be applied sensitively.

³⁵ SEC(2004) 1628.

Table 3

Benefits	Efficiencies in implementation of Common Visa Policy	Reductions in fraud and visa shopping	Increased efficiency of border checks	Reductions in illegal migration / facilitation of the Dublin Regulation	Contribution towards internal security	Increased efficiencies for bona fide travellers	Other spin offs
No VIS	-	√*	√*	√*	√*	-	-
Entry-exit system	√√√	√√√	√√√	√√√	√√	√√√	√√√
VIS without biometrics	√√	√√	√√	√	√	√√	√
VIS with biometrics	√√√	√√√	√√√	√√	√√	√√√	√√√

5.5.2 The set of evaluation criteria

The set of evaluation criteria you use will depend on the policy area(s) and the nature of the objectives. The most important criteria are of course directly related to the objectives. In simple terms: the options should achieve the objectives, and do so with a minimum of undesirable side effects (such as compliance costs, administrative burdens etc.). In relation to the objectives, the criteria for evaluating the policy options are:

- **Effectiveness:** The extent to which options achieve the objectives of the proposal.³⁶
- **Efficiency:** The extent to which objectives can be achieved for a given level of resources/at least cost (cost-effectiveness).³⁷
- **Coherence:** The extent to which options are coherent with the overarching objectives of EU policy, and the extent to which they are likely to limit trade-offs across the economic, social, and environmental domain.

To rank the options, you should analyse:

- the performance of the different policy options in achieving the core policy objective
- the balance of positive and negative impacts associated with the preferred option and possible alternatives

The first step will be to focus on the performance of the policy option, in terms of its effectiveness, efficiency and coherence with overarching EU policy objectives. You should start by identifying the option that comes closest to achieving the core objectives. In a preliminary ranking of options this should be the first criterion. You could conclude the analysis here if there were no implementation costs or other negative side effects. Unfortunately this is rarely the case. In a second step you should therefore look at the costs that are directly associated with implementation of the policy options. In many cases this may show trade-offs that are relevant for the political choices that need to be

³⁶ In the case of regulatory instruments you should, for example, assess the extent to which addressees are likely to accept/comply with regulatory requirements. Chapter 5.4.5 has more detailed guidance on this.

³⁷ You must assess this criterion for expenditure programmes (c.f. Financial Regulation/ Implementing Rules).

made. The key values (in terms of marginal costs and benefits) should be calculated or estimated. In some cases this may lead to the development of variations or sub-options.

In the next step of the selection process, you should list the expected positive and negative impacts of the policy options, including unintended side-effects. This presentation should be made in quantitative terms for all variables for which this is feasible, expressed in deviations from the baseline scenario. It is often useful to illustrate this in a table or a graph.

The most effective and efficient policy option will usually also produce the highest net benefits, and any option that convincingly passes this dual test will be credible. However, if the differences in net benefits are not significant, or cannot be sufficiently quantified or supported by evidence, you may need to reconsider the design of the options.

Proposed options that cannot be convincingly shown to produce net benefits should normally be discarded on the basis of the impact assessment.

The table below is one way to present a summary comparison of the policy options in terms of their effectiveness, efficiency, and coherence.

	Effectiveness	Efficiency	Coherence
Option A	Achievement of policy objectives 'A', and 'B'	'X' resources needed to achieve level of impacts 'y'	Good balance of positive and negative (un)intended/(in)direct impacts in economic, social and environmental matters
Option B	Achievement of policy objective 'A' only	'2X' resources needed to achieve level of impacts 'y'	Positive economic impacts; negative unintended impacts on the environment, namely...
Option C

5.5.3 How to assess budgetary cost-effectiveness

Where an initiative involves expenditure, it may be appropriate to carry out a *cost-effectiveness analysis*. This analysis will relate the total expenditure to the effects it produces (for example, the budget cost per job). A measurement of this type will allow you to compare and rank different options on their budgetary cost-effectiveness. You should consider the following types of cost when assessing budgetary cost-effectiveness:

- direct financial outlays (to beneficiaries or third parties) from the EU budget.
- financial outlays from Member State budget which are directly tied to the EU expenditure or which are a direct consequence of the EU spending.
- human resources needed to manage the intervention.
- administrative costs for the Commission and public authorities (e.g. external assistance in the form of feasibility or evaluation studies, informatics costs etc).

Budgetary cost-effectiveness needs to be distinguished from the criteria of effectiveness and efficiency discussed in chapter 3.3. Budgetary cost-effectiveness deals only with the expenditure element of each your options, whereas effectiveness and criteria deal much more broadly with each option in its entirety.

More information on cost-effectiveness analysis can be found in a study on DG Budget's Europa website:

(http://ec.europa.eu/budget/library/documents/evaluation/studies/cea_finalreport_en.pdf).

5.5.4 Ranking the options

The impact assessment process will in many cases lead to the conclusion that one option best achieves the initiative's objectives in terms of effectiveness, efficiency and coherence. In other cases it may not be possible or desirable to generate clear-cut conclusions for the final policy choice. Identifying a preferred option is not a strict requirement. Nevertheless, in these cases the options should also be ranked according to relevant criteria and, as an aid to decision-making, the results and the alternative options considered should be presented in a transparent and understandable way. This allows decision-makers to examine the trade-offs between affected groups and/or between the impacts on the social, economic and environmental dimensions. It also allows the design of any proposal to be improved to help minimise trade-offs, to identify accompanying measures to mitigate any negative effects, and to maximise the opportunities for a 'win-win' outcome.

5.6 Arrangements for future monitoring and evaluation

Identify *core progress indicators* for the key objectives of the possible intervention.

Provide a broad outline of *possible monitoring and evaluation arrangements*.

Policymakers need to be able to verify if implementation is 'on track', and the extent to which the policy is achieving its objectives. When a policy is not achieving its objectives, they also need to know whether this is the result of problems with the design of the policy, or of poor implementation e.g. was the problem analysis accurate? Were the objectives relevant and attainable? Was implementation entrusted to parties capable of understanding the policy and willing to apply it to the letter? Is inadequate implementation the result of weak administrative capacity?

Monitoring and evaluation arrangements, together with indicators, provide valuable information in this regard. The impact assessment should therefore outline the monitoring and evaluation arrangements and define core indicators for the main policy objectives. It is not necessary to do this in detail for all the options examined in the impact assessment. This will be done after the political choice of the most appropriate policy option has been made, as this is the last step in the policy design process.

It does make sense, however, to define some core indicators for the key policy objectives (i.e. for the so-called 'general objectives') as these are valid for all policy options.

Indicators must serve a clear purpose, i.e. measuring to what extent a policy has been properly implemented and its objectives achieved. Another important factor in choosing your indicators is the ease with which relevant data can be collected; collecting data should not be more costly than the value of the information they provide.

Where a preferred option has been identified, you should:

- 1. describe briefly how the data needed for monitoring are to be collected and**
- 2. outline the nature, frequency and purpose of subsequent evaluation exercises⁵¹.**

Questions to be addressed include:

- What will the monitoring data and evaluation findings be used for?**
- Who are the key actors in providing and using such information? (e.g. the Commission, Member States, intermediaries such as Agencies, operators/beneficiaries, etc)?**
- In general terms, what will be the roles of these actors? How will information be shared and eventually aggregated?**
- To what extent do monitoring/evaluation structures already exist? Does new capacity need to be put in place?**
- Is the baseline situation sufficiently well known or will further data collection be necessary once the proposal has been adopted?**

Annex 13 provides more detailed guidance (including examples) on indicators, monitoring and evaluation.